

Fig. 1

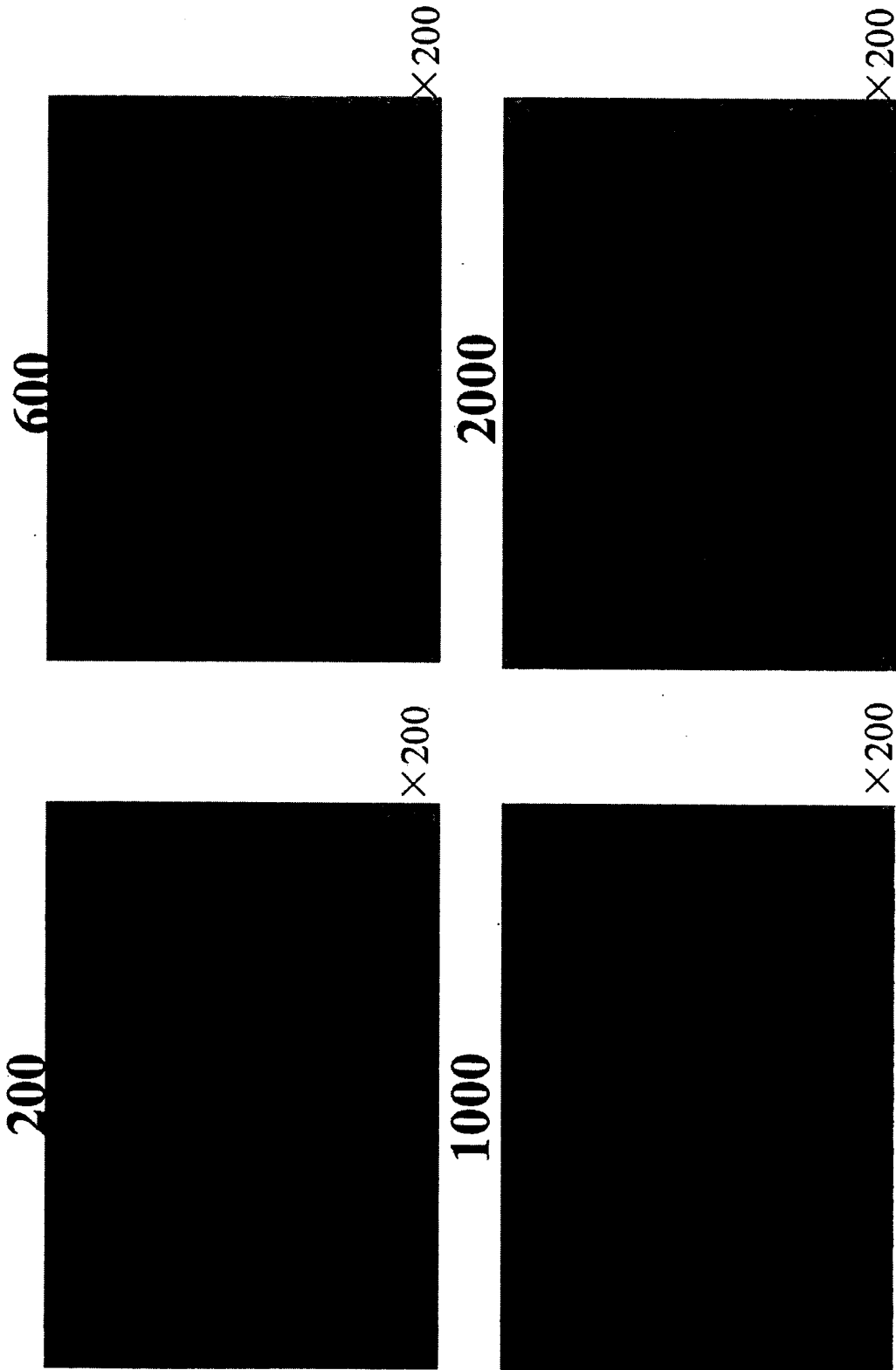
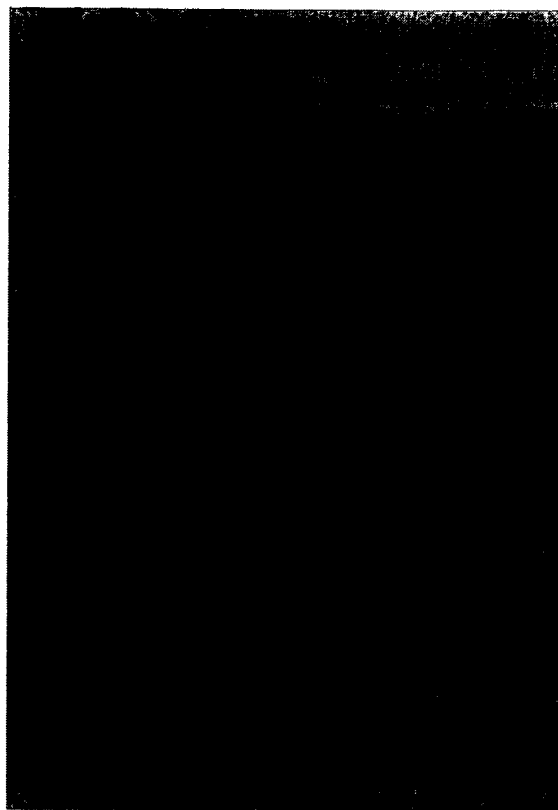


Fig. 2

PEG1000



With agitation
×200



Without agitation
×200

BEST AVAILABLE COPY

Fig. 3

X40

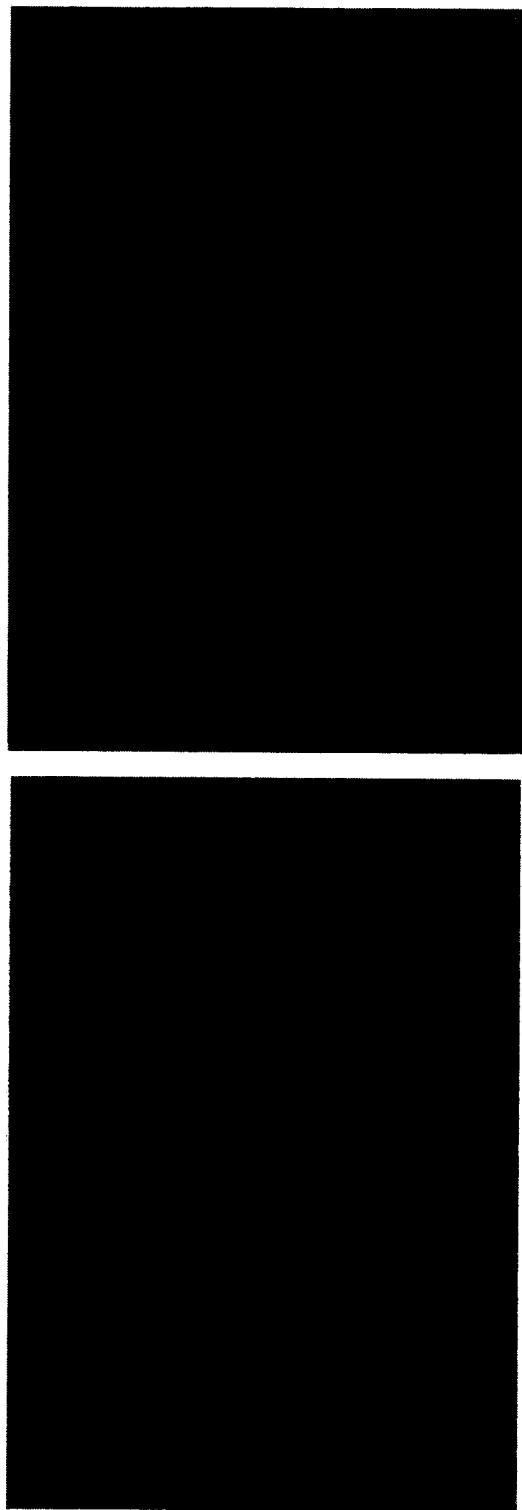


BEST AVAILABLE COPY

Fig. 4

DNase

PEG2000



DNase (-)

DNase (+)

Fig. 5



BEST AVAILABLE COPY

Fig. 6



BEST AVAILABLE COPY

Fig. 7

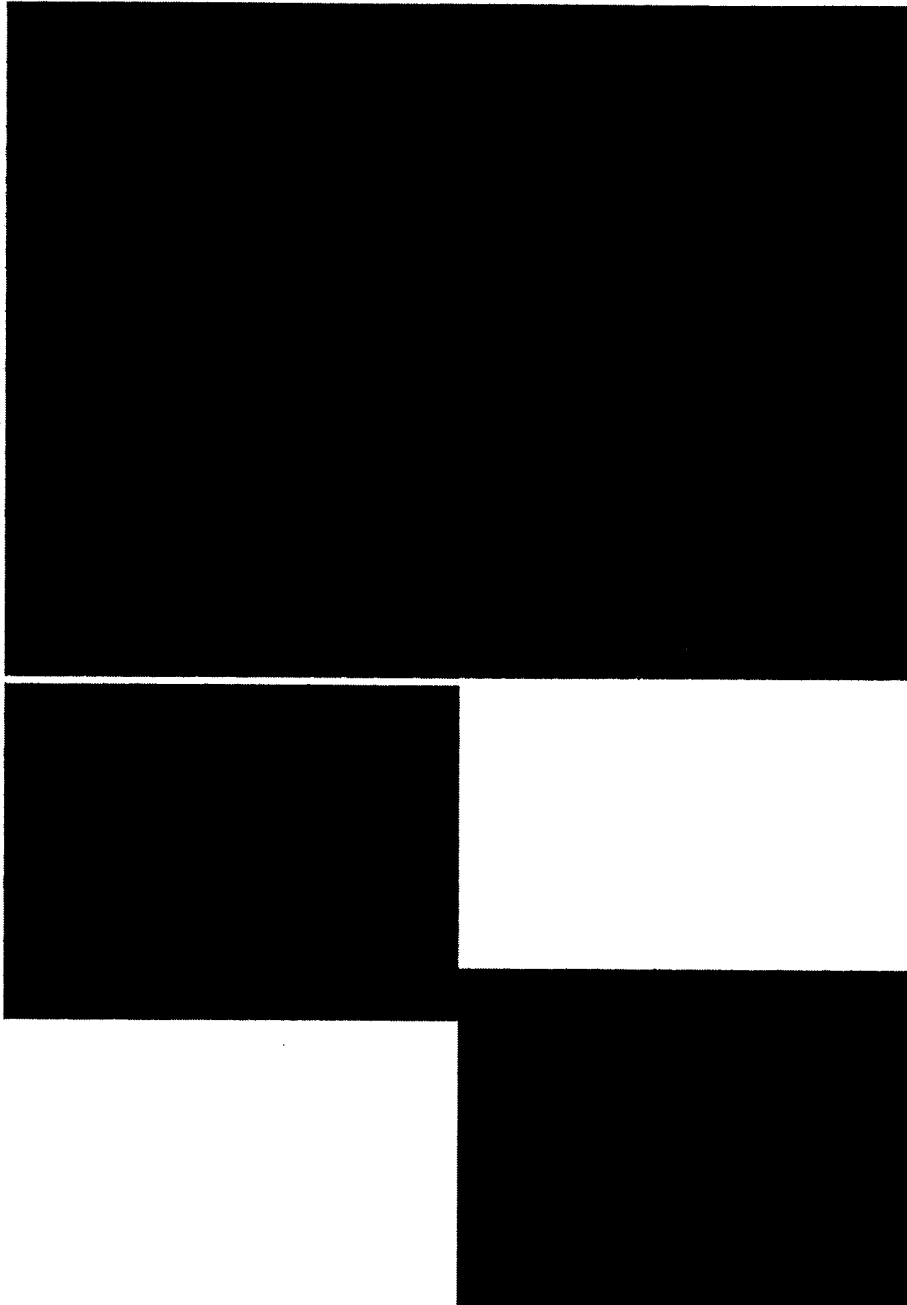


Fig. 8



Fig. 9

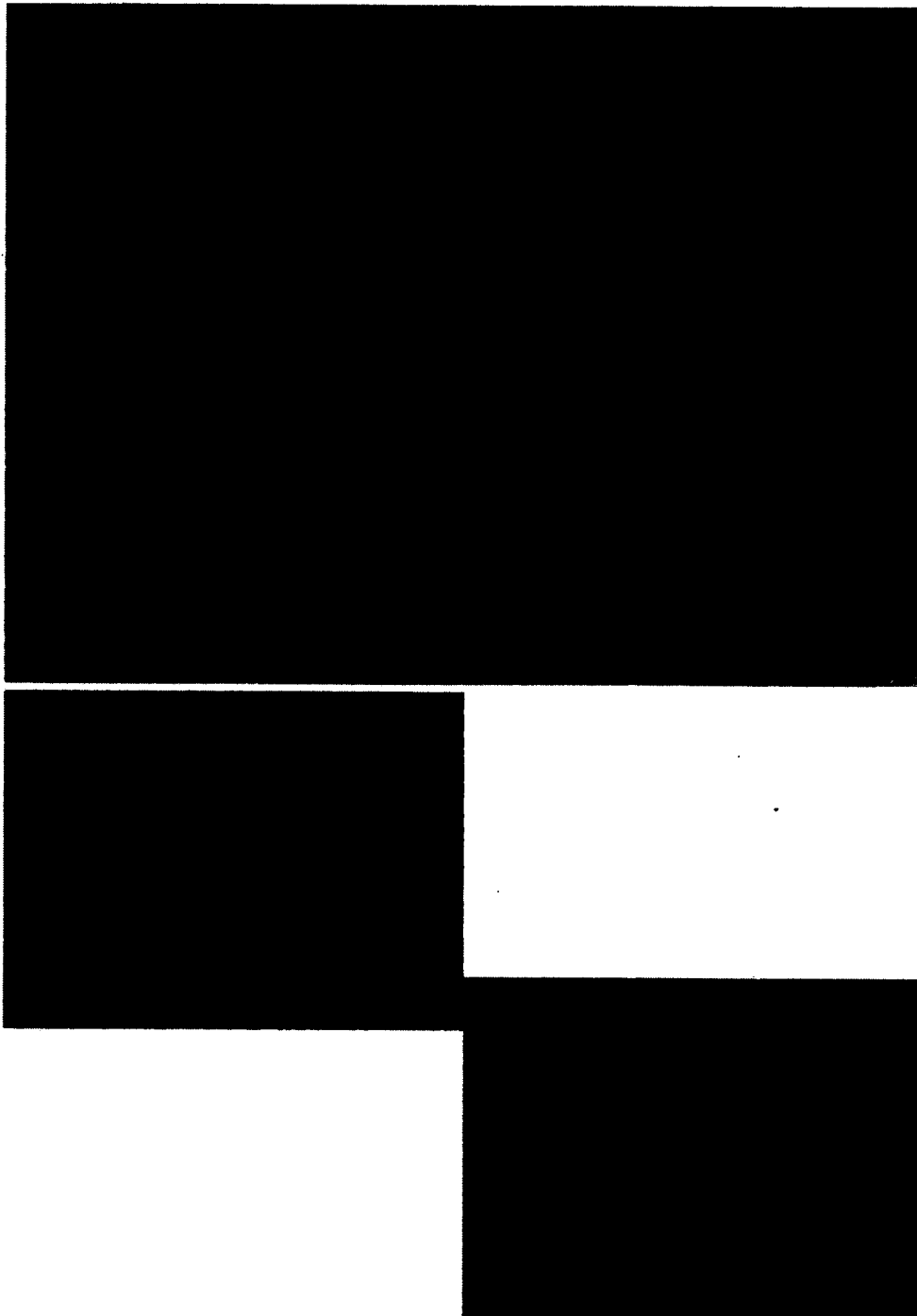


Fig. 10

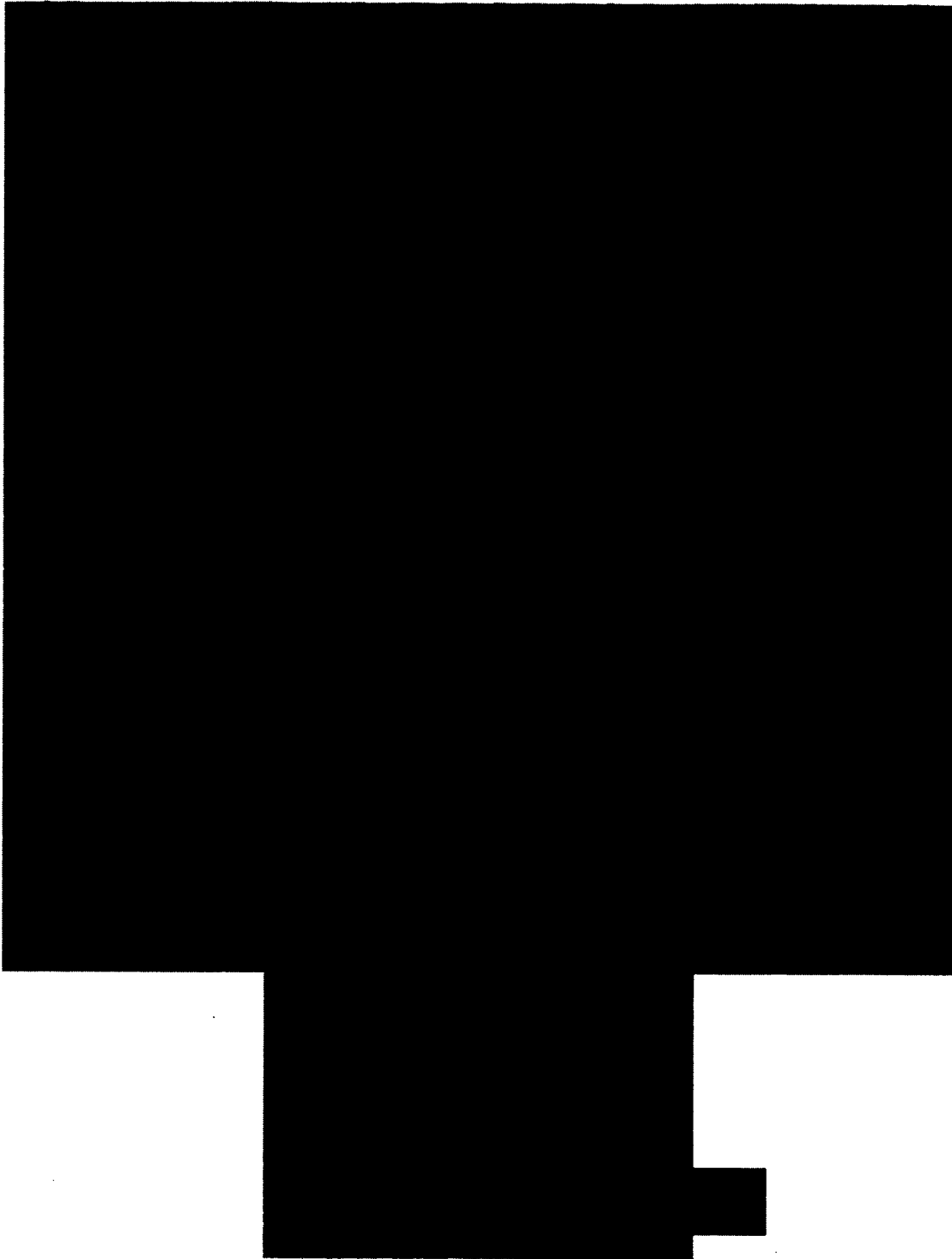


Fig. 11



Fig. 12

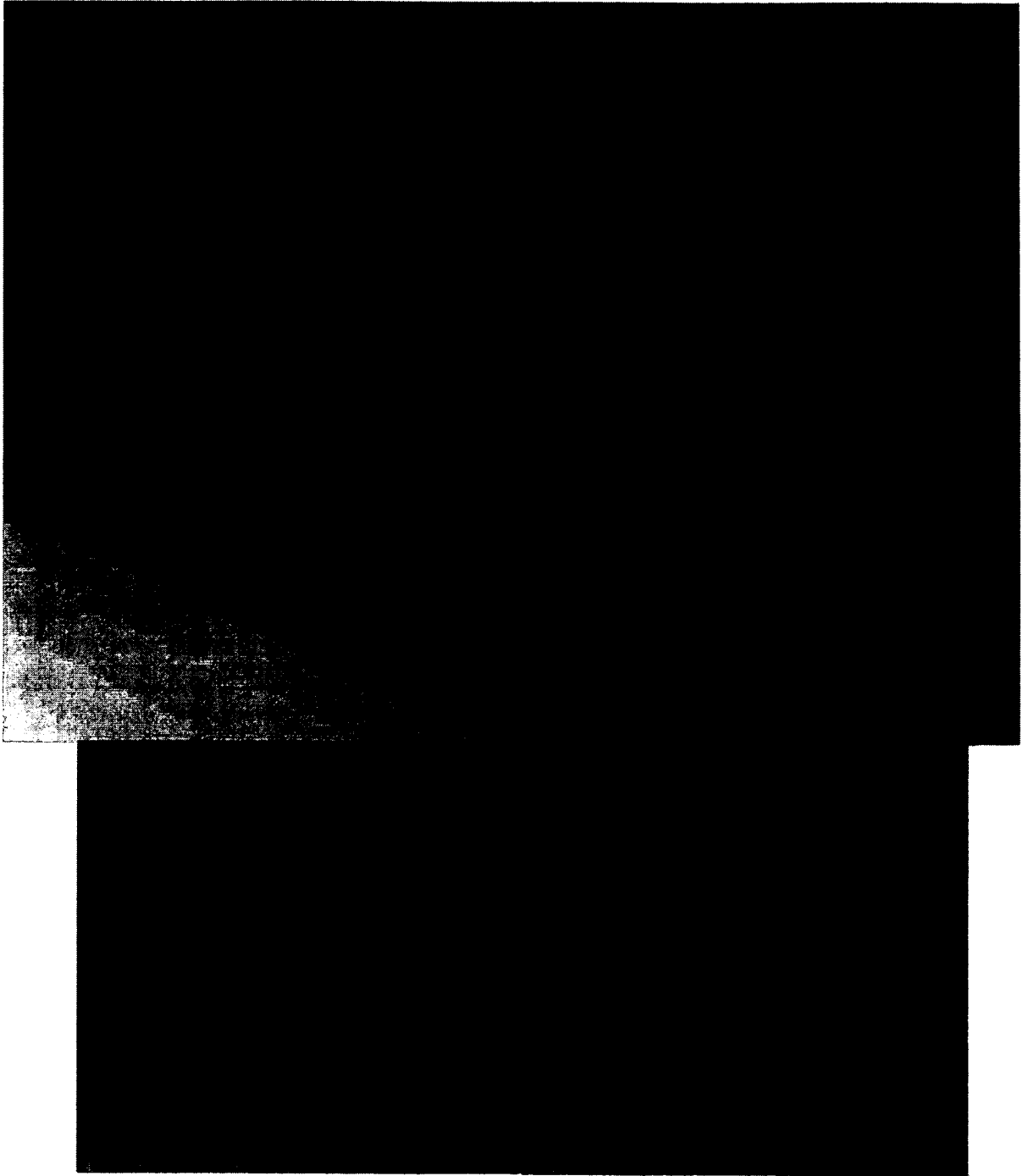


Fig. 13



Fig. 14



Fig. 15



100

Fig. 16

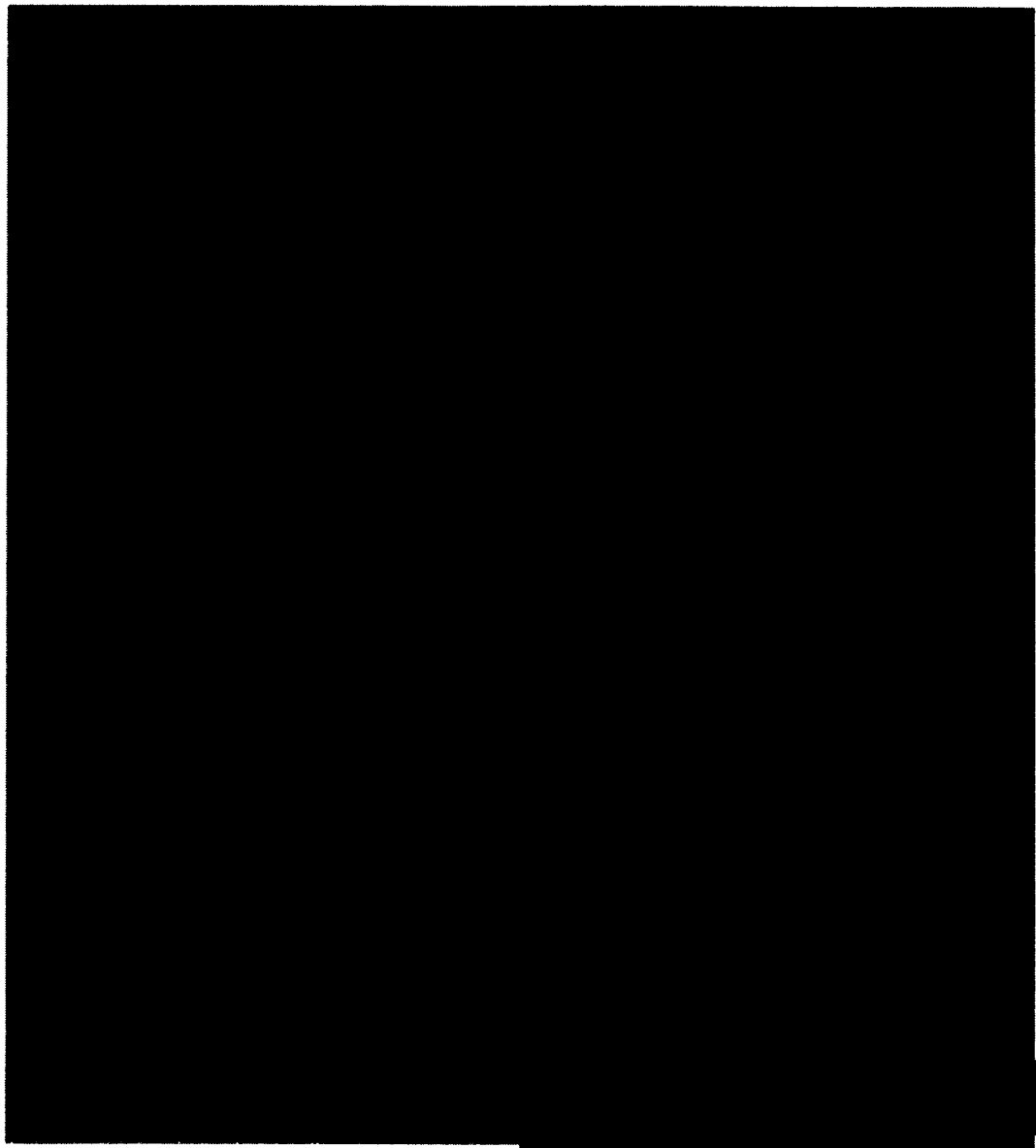


Fig. 17

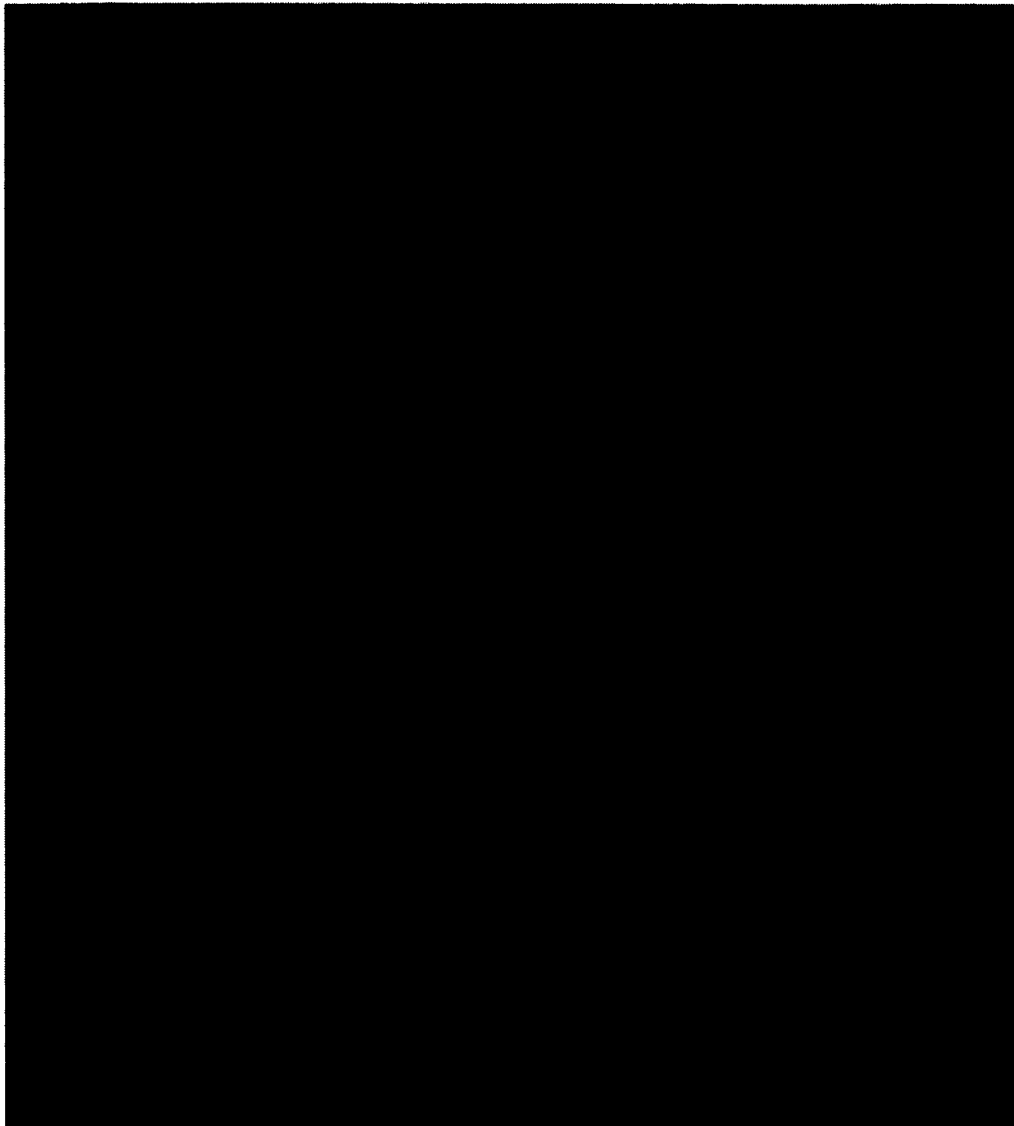


Fig. 18

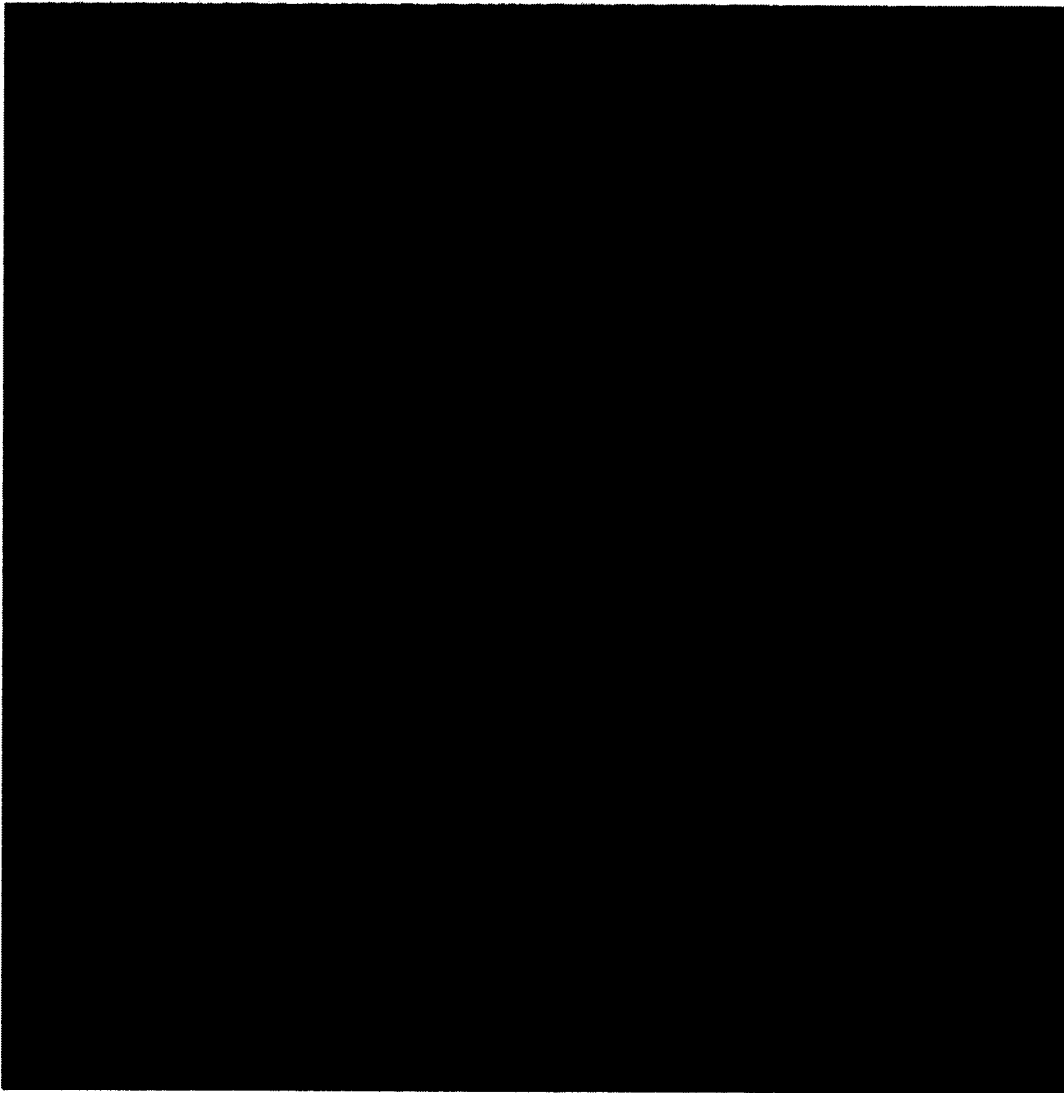


Fig. 19

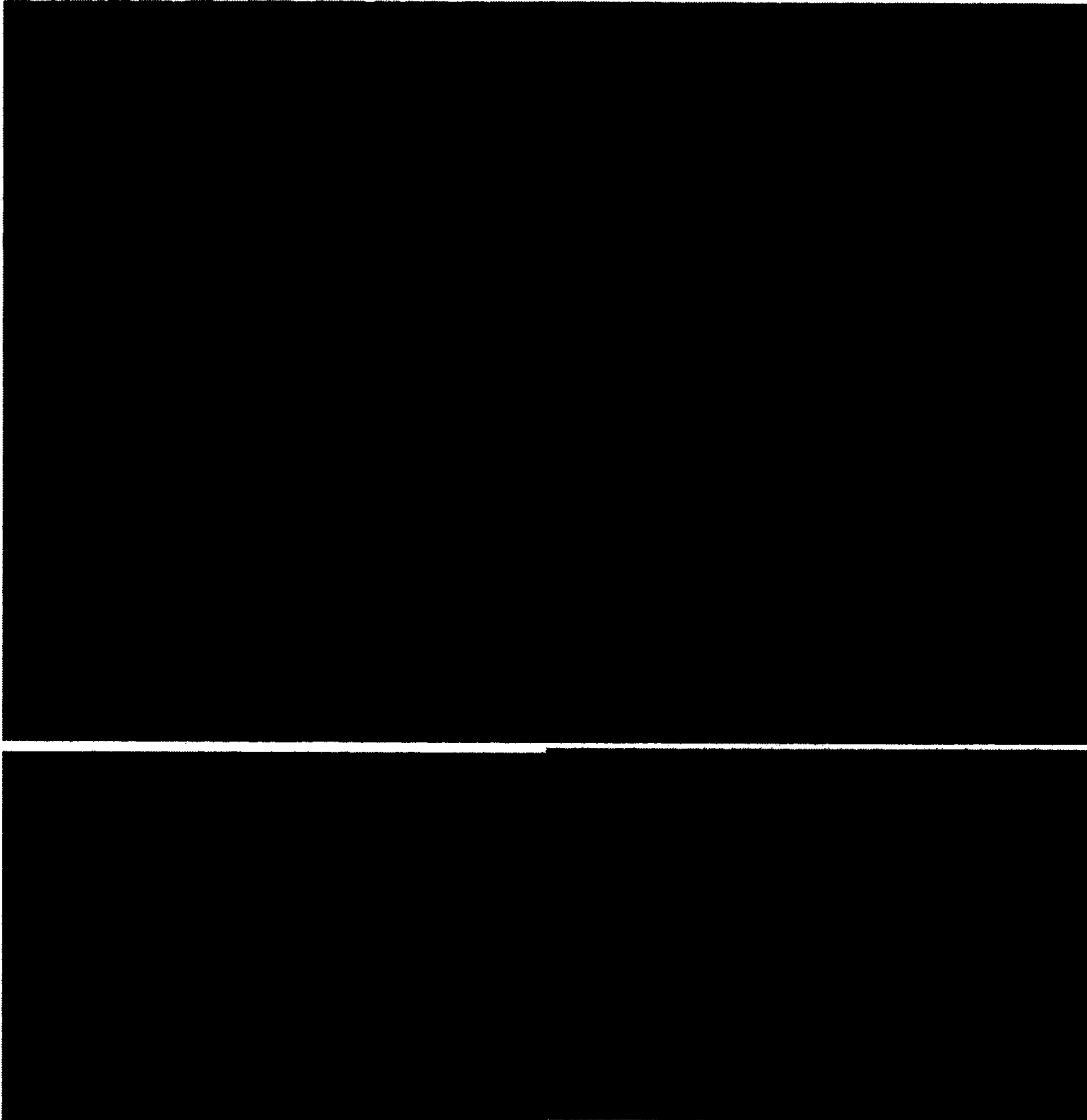


Fig. 20

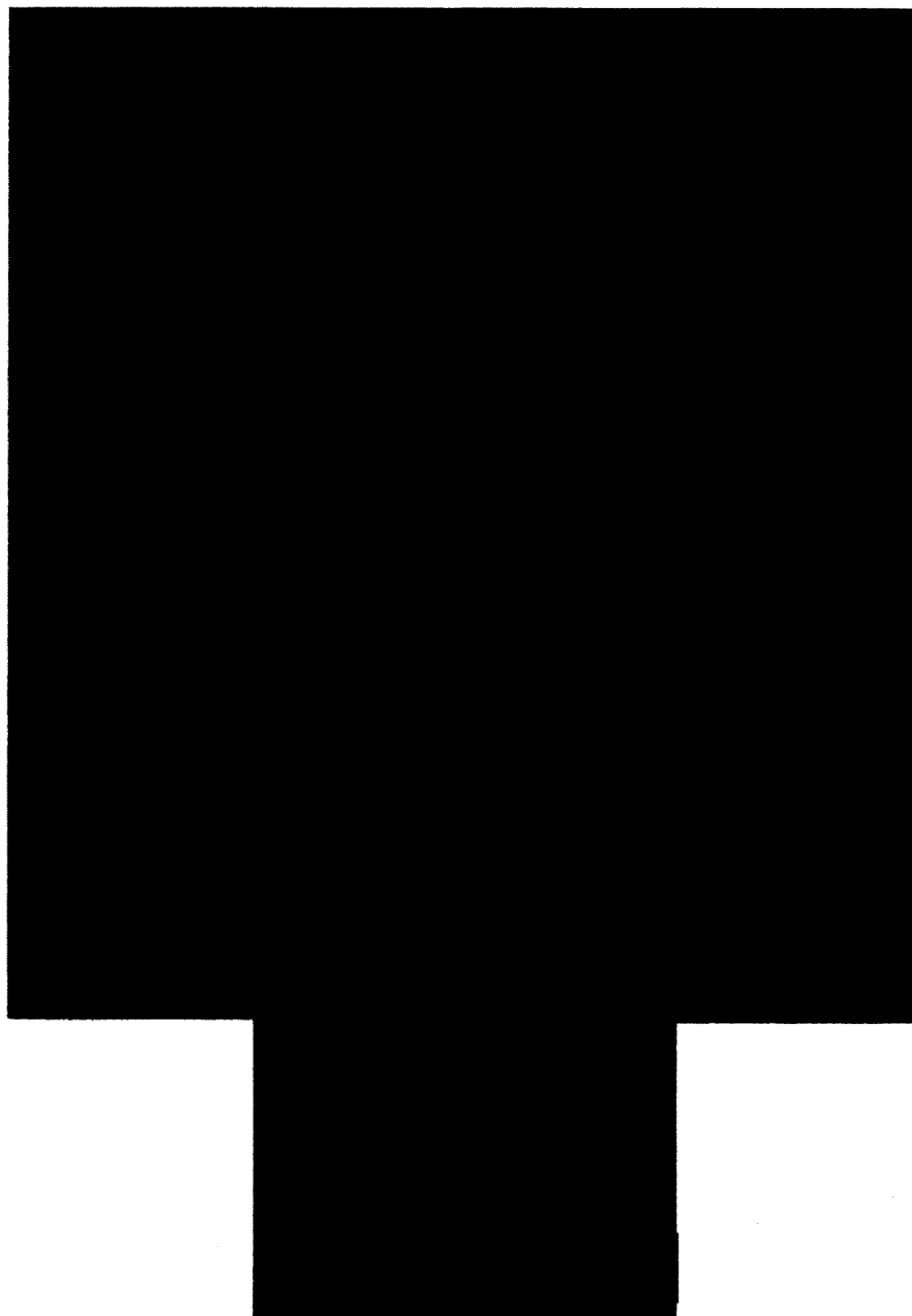


Fig. 21

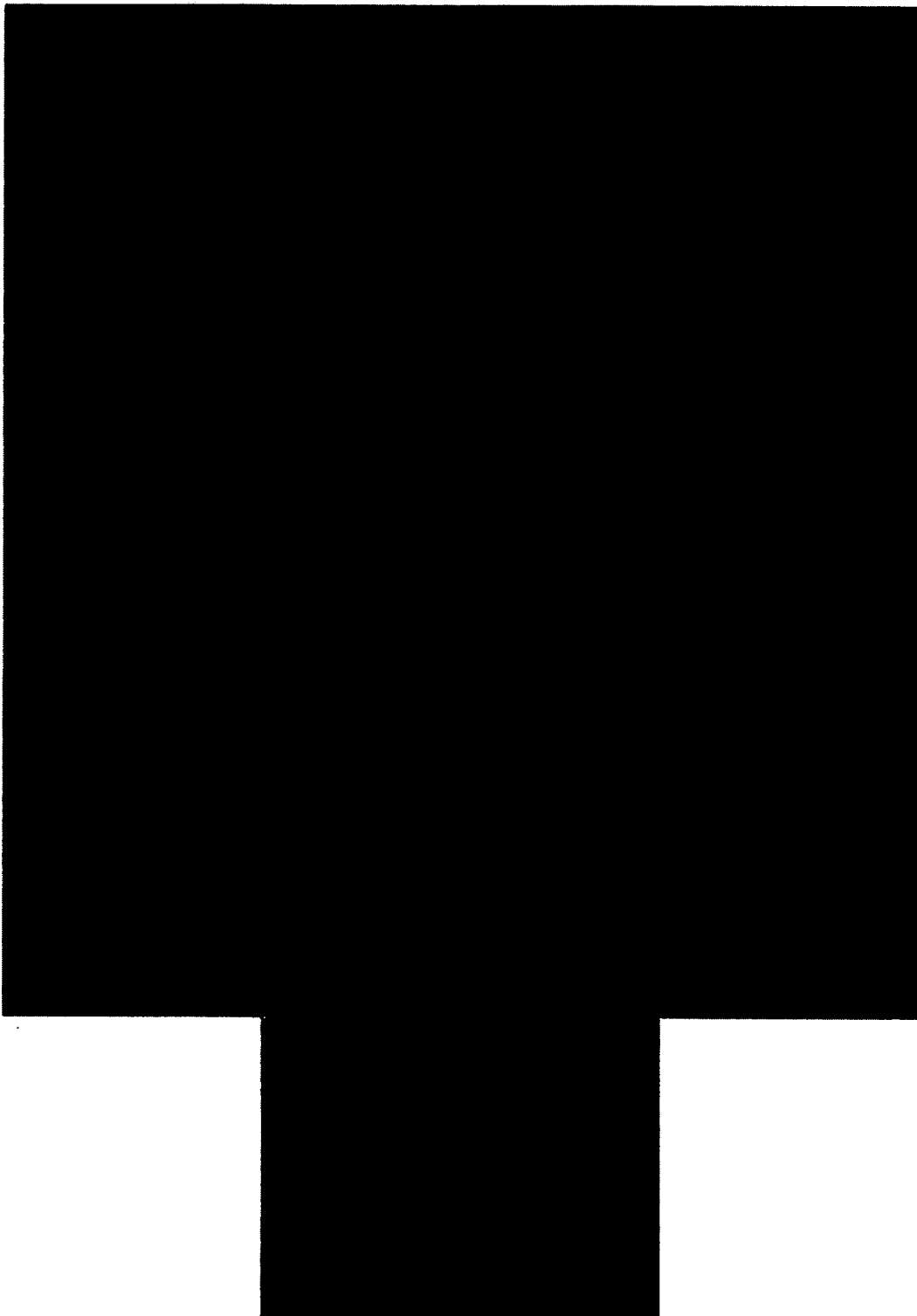


Fig. 22



Fig. 23



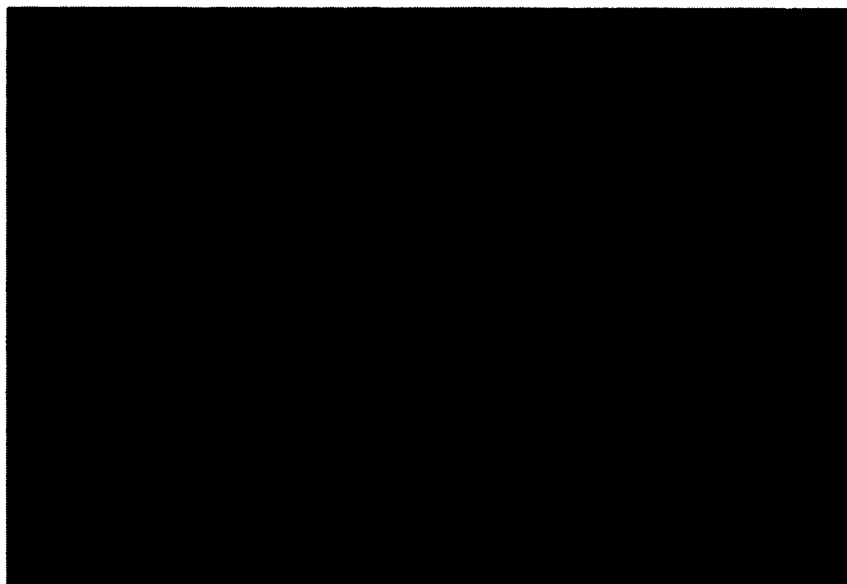
Fig. 24



Fig. 25



Fig. 26



50KGy

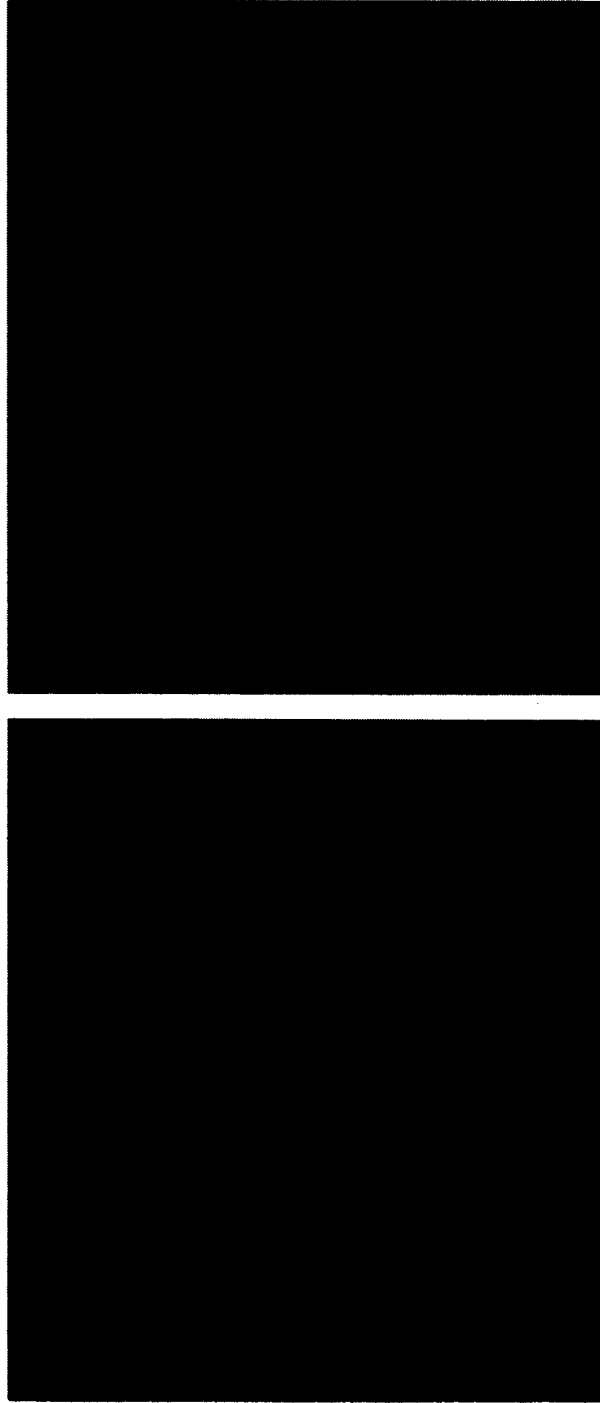
Fig. 27



100KGy

Fig. 28

γ -ray 130KGy + DNAase



HE staining X200

Fig. 29

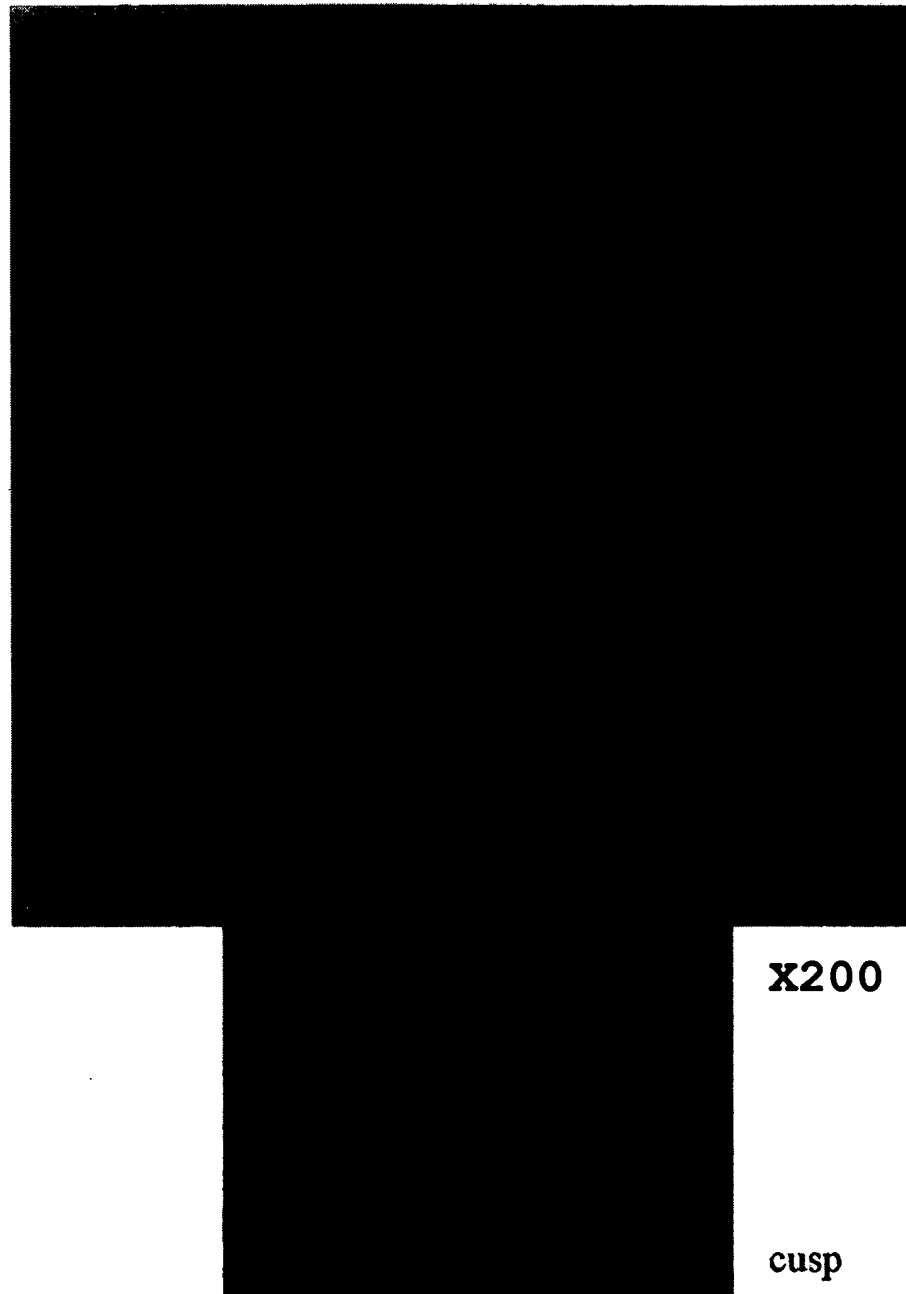
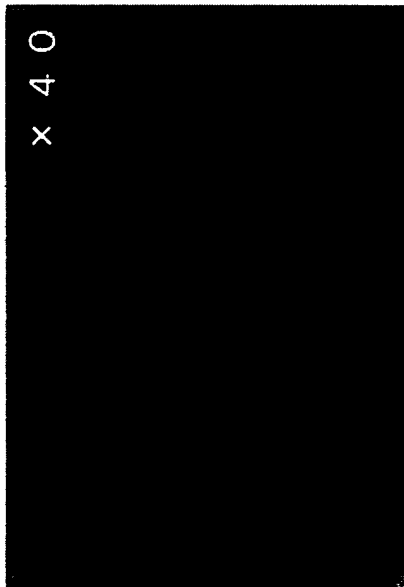
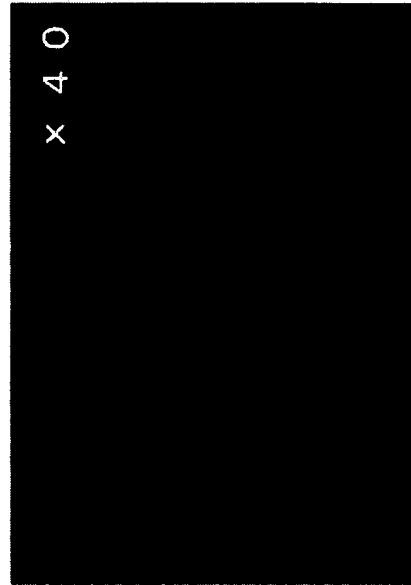


Fig. 30A

Valve PEG + γ :decellularization effects



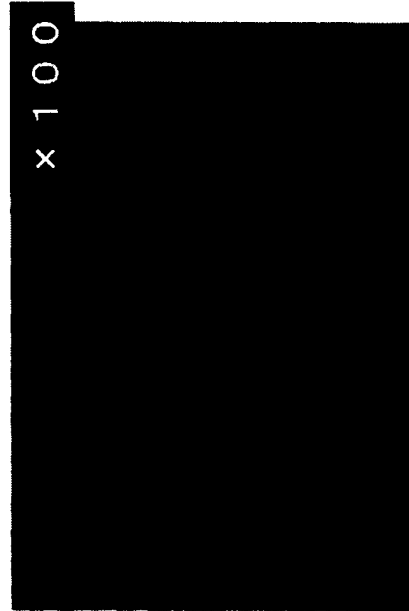
Treatment : PEG + γ -ray 100kGy
Object : valve
Magnification : X40



Treatment : PEG + γ -ray 100kGy
Object : valve
Magnification : X40



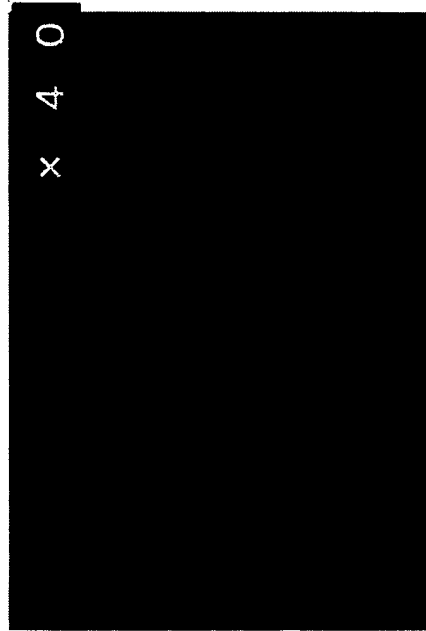
Treatment : PEG + γ -ray 100kGy
Object : valve
Magnification : X100



Treatment : PEG + γ -ray 100kGy
Object : valve
Magnification : X100

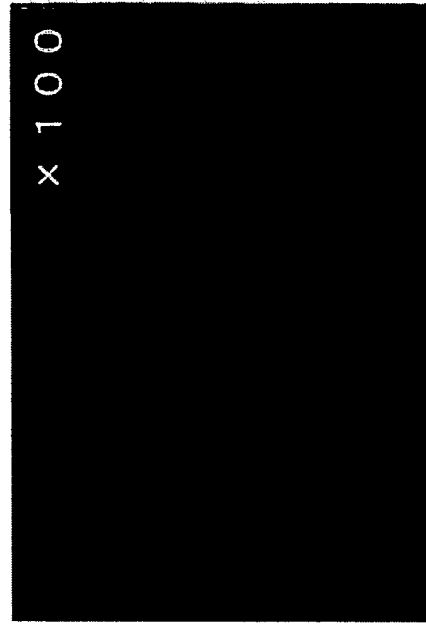
Fig. 30B

valve cusp PEG + γ : decellularization effects



X 40

Treatment : PEG + γ -ray 100kGy
Object : valve cusp
Magnification : X40



X 100

Treatment : PEG + γ -ray 100kGy
Object : valve cusp
Magnification : X100

Fig. 31

PEG

Results of tensile strength tests

Testing machine		RTC series			Type of testing		Extension		
Load in full-scale		5 kgf			Rated capacity of load cell		100 N		
Range of load		40 %RO			Rated capacity of the extensometer		20 cm		
Range of the extensometer		unapplied			Test Speed		10.0 mm/mdn		
Recording speed off					Rigidity of the testing machine		0 mm/kgf		
Midpoint (load)		0	0	0	Midpoint (extension)		0	50	80
N		0	0	0	cm		0	0	0
Analysis of Elastic moduli		Interval		1	50	Initial length Distance between chunks		10 mm	
		Pitch		1 %max		origin in extension initial load point		0.03 N	
slack correction		applied			determination of rupture point		0.5 N		
Storing SS curve		ON							

TestID=120	Maximum load	Maximum load	Rupture load	Rupture load	Maximum Extension	Elastic Modulus
Test No.	kgf	N	kgf	N	mm	MPa
1	1.3522	13.260	1.0889	10.678	18.227	2.3930
2	1.3048	12.797	1.0285	10.088	20.987	1.8916
3	0.9980	9.7870	0.9281	9.1012	14.327	1.8013
4	1.0020	9.8281	0.7277	7.1385	16.367	1.5781
5	0.7638	7.4879	0.7340	7.1981	4.2267	4.7653
Average	1.0841	10.632	0.9010	8.8380	14.427	2.4855
JIS weighted avg	1.2675	12.430	1.0186	9.9888	18.459	3.4698
Median	1.0020	9.8281	0.9281	9.1012	16.227	1.8916
Maximum	1.3522	13.260	1.0889	10.678	20.987	4.7653
SD(n-1)	0.2437	2.3897	0.1656	1.6239	6.2066	1.3090
SD(n)	0.2180	2.1374	0.1481	1.4525	5.5513	1.1708

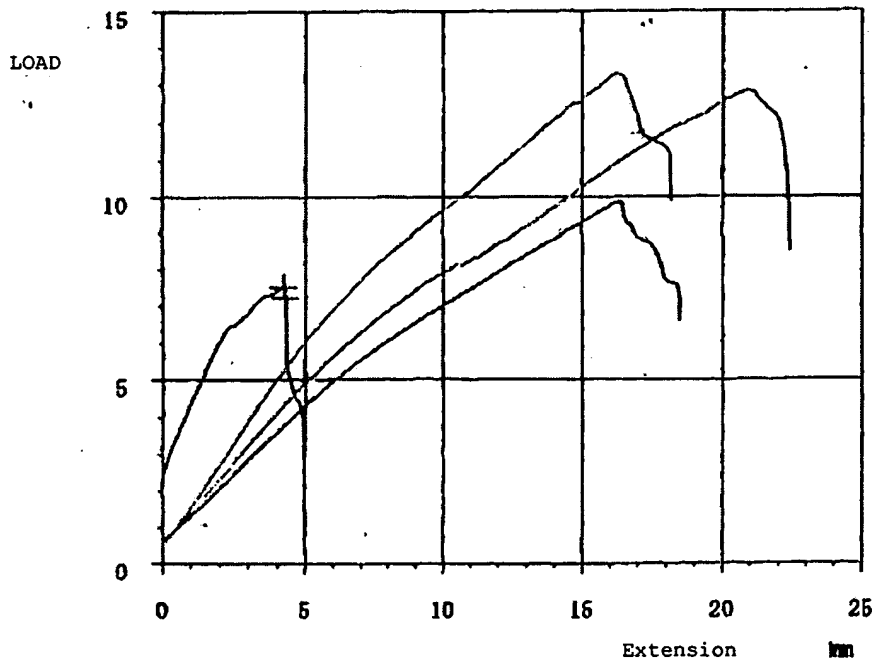


Fig. 32

Results of tensile test of native canine aorta.

Testing machine	RTC series			Type of testing	Extension		
Load in full-scale	5 kgf			Rated capacity of load cell	100 N		
Range of load	40 %RO			Rated capacity of the extensometer	20 cm		
Range of the extensometer	unapplied			Test Speed	10.0 mm/min		
Recording speed off				Rigidity of the testing machine	0 mm/kgf		
Midpoint (load)	0	0	0	Midpoint	0	50	60
N	0	0	0	(extension)	cm	0	0
Analysis of Elastic moduli	Interval	1	50	Initial length Distance between chunks	10 mm		
slack correction	Pitch	1 %max		origin in extension initial load point	0.03 N		
Storing SS curve	applied			Determination of rupture point	0.5 N		
	ON						

TestID-37	Maximum load	Maximum load	Rupture load	Rupture load	Maximum Extension	Elastic Modulus
Test No.	kgf	N	kgf	N	mm	MPa
1	0.7591	7.4445	0.5038	4.9404	27.887	1.0918
Average	0.7591	7.4445	0.5038	4.9404	27.887	1.0918
JIS weighted avg	0.7591	7.4445	0.5038	4.9404	27.887	1.0918
Median	0.7591	7.4445	0.5038	4.9404	27.887	1.0918
Maximum	0.7591	7.4445	0.5038	4.9404	27.887	1.0918

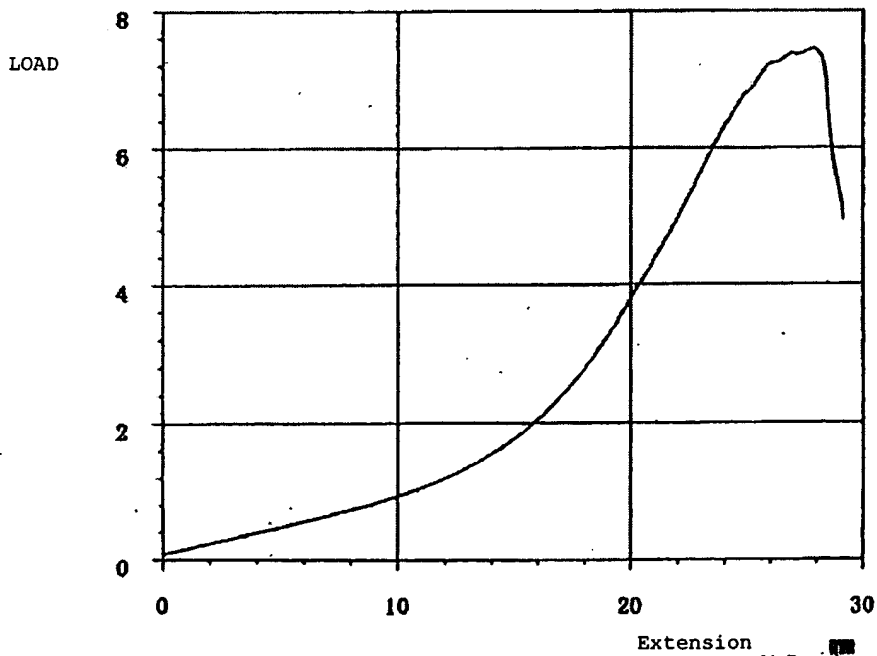


Fig. 33

results of tensile test of conventional artificial valves by means of decellularization cell method by SDS

Testing machine	RTC series			Type of testing	Extension		
Load in full-scale	5 kgf			Rated capacity of load cell	100 N		
Range of load	40 NRO			Rated capacity of the extensometer	20 cm		
Range of the extensometer	unapplied			Test Speed	10.0 mm/min		
Recording speed off				Rigidity of the testing machine	0 mm/kgf		
Midpoint (load)	0	0	0	Midpoint (extension)	0	50	80
N	0	0	0	cm	0	0	0
Analysis of Elastic moduli	Interval	1	50	Initial length	Distance between chunks		
slack correction	Pitch	1 %max		origin in extension	initial load point		
Storing SS curve	applied			Determination of rupture point	0.03 N		
	ON				0.5 N		

TestID=17	Maximum load	Maximum load	Rupture load	Rupture load	Elastic Modulus
Test No.	kgf	N	kgf	N	MPa
1	1.0401	10.200	1.0284	10.085	2.5168
2	0.7095	6.9574	0.6856	6.7231	1.4561
3	0.7142	7.0038	0.6339	6.2164	1.4976
4	0.8572	8.4063	0.8503	8.3387	1.6630
5	0.6693	6.5839	0.6613	6.4847	1.1928
Average	0.7981	7.8263	0.7718	7.5696	1.6653
JIS weighted avg.	0.9196	9.0180	0.9040	8.8649	2.0527
Median	0.7142	7.0038	0.6856	6.7231	1.4976
Maximum	1.0401	10.200	1.0284	10.085	2.5168
SD(n-1)	0.1529	1.4996	0.1663	1.6313	0.6050
SD(n)	0.1368	1.3413	0.1488	1.4591	0.4517

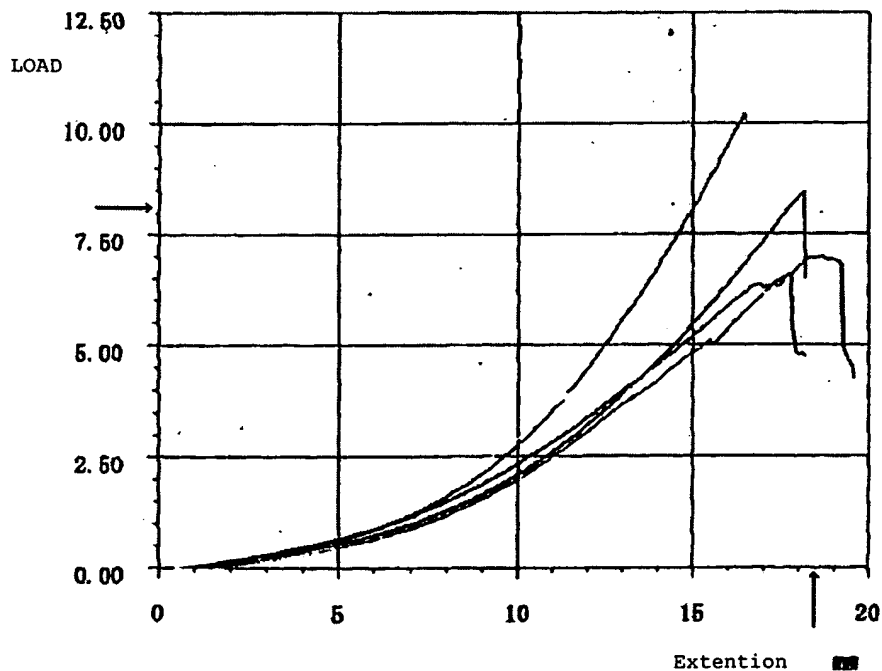


Fig. 34

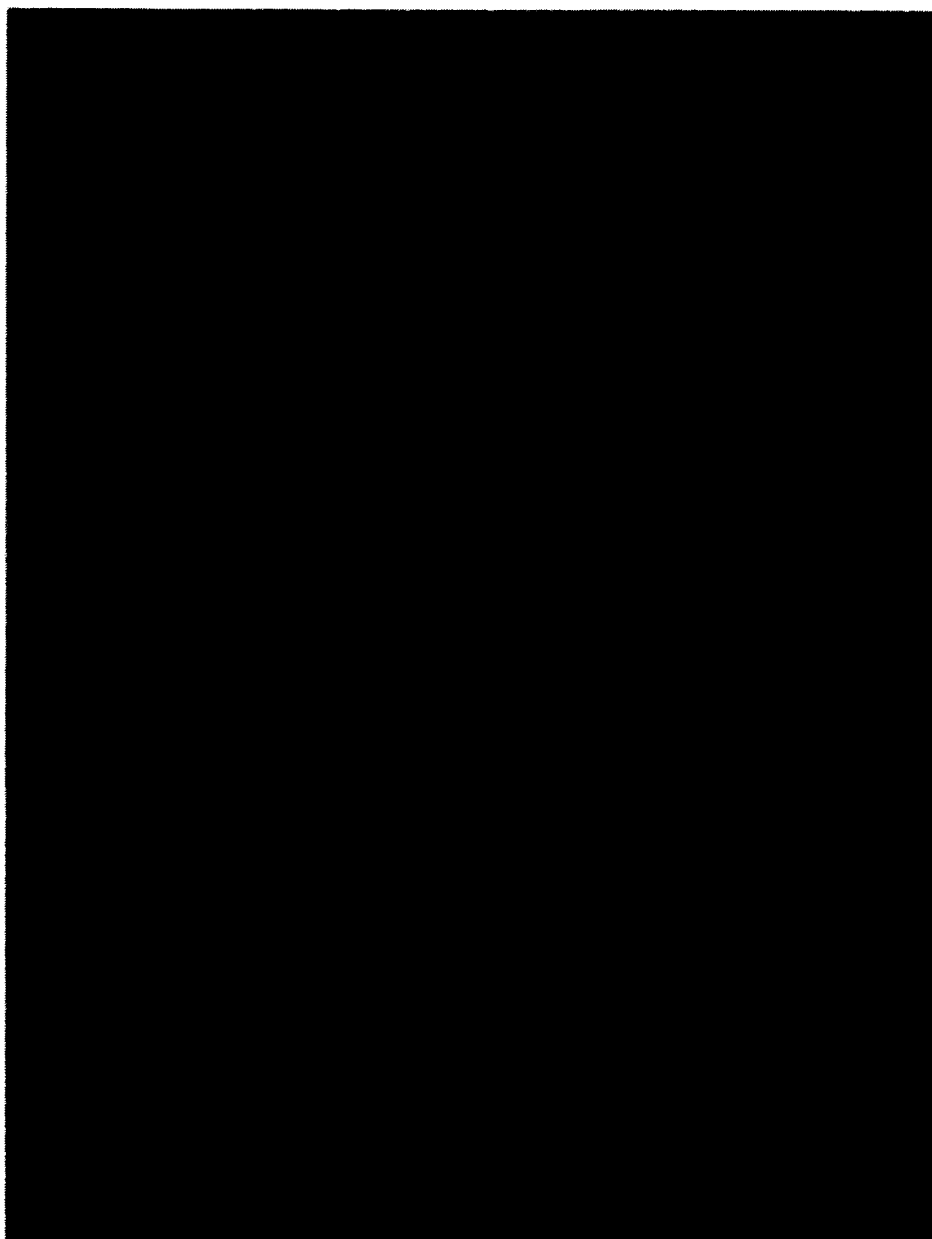
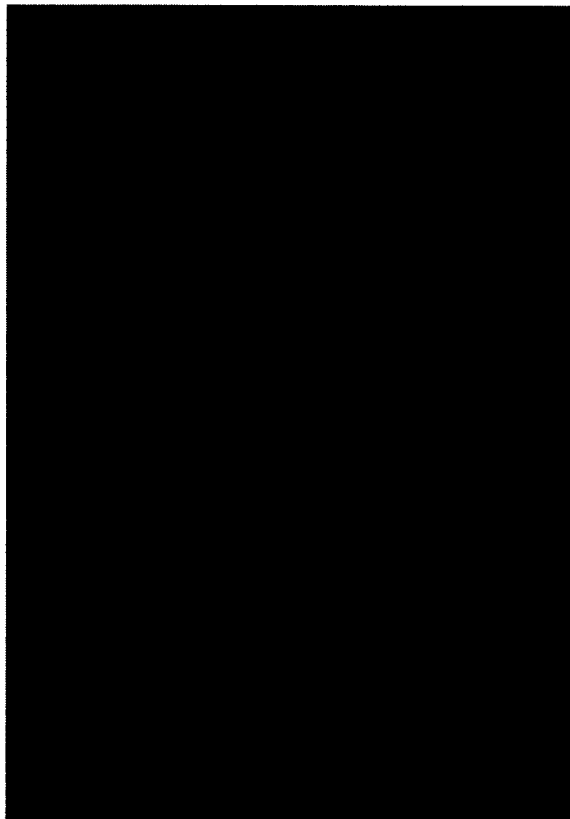


Fig. 35



x 200

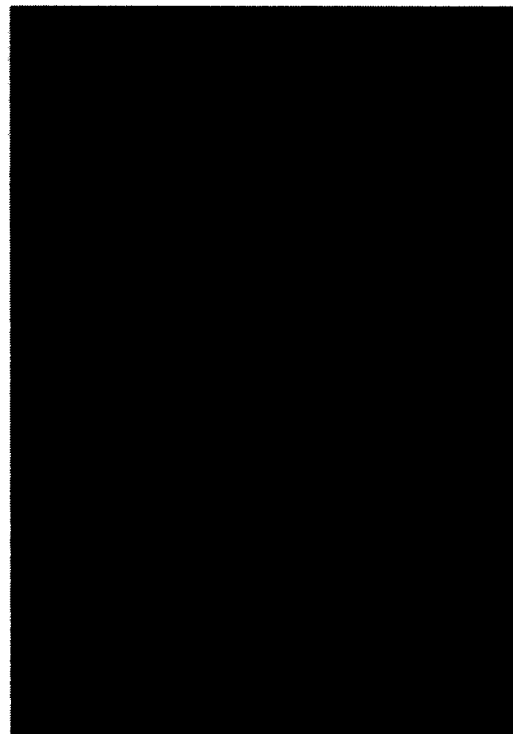


x 100

Fig. 36



x 100



x 40

Fig. 37

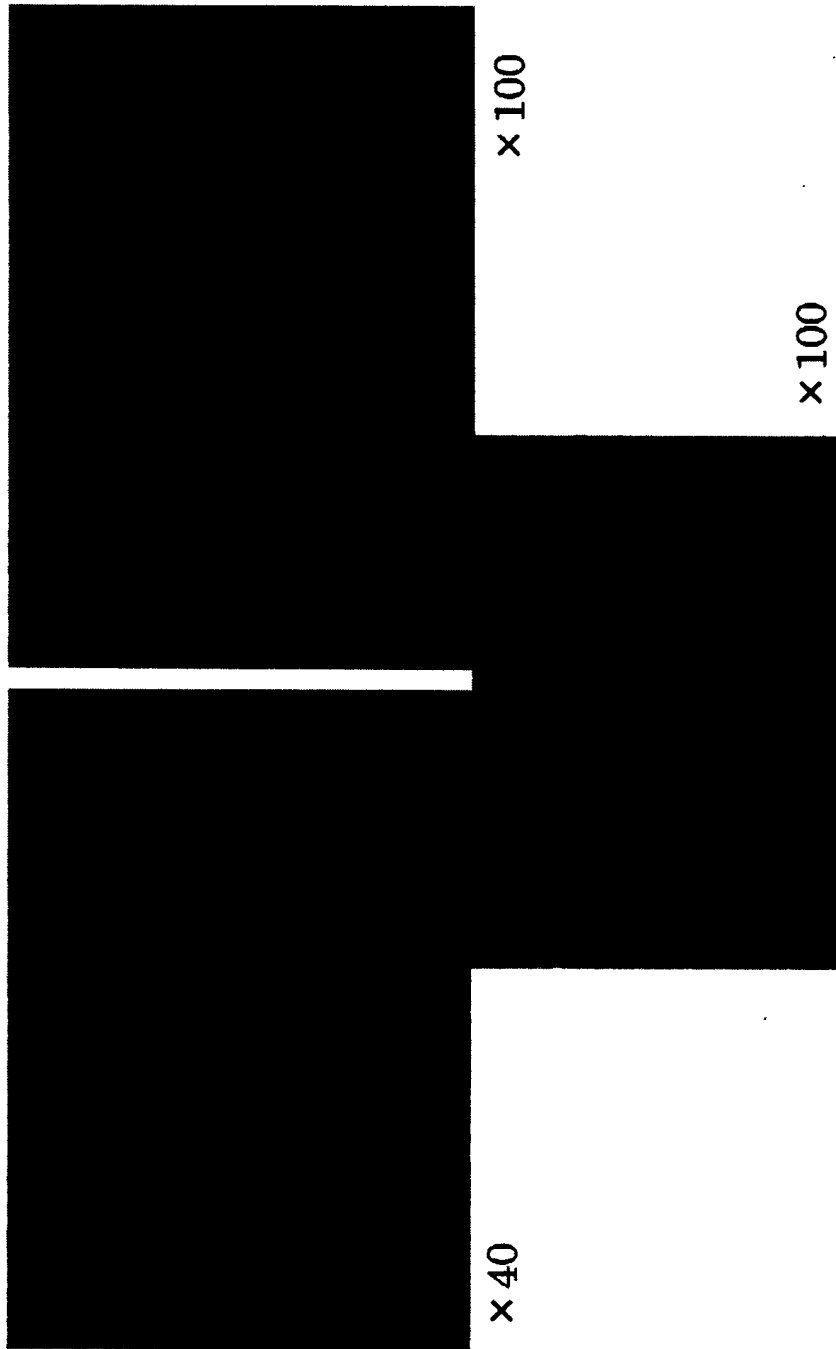


Fig. 38

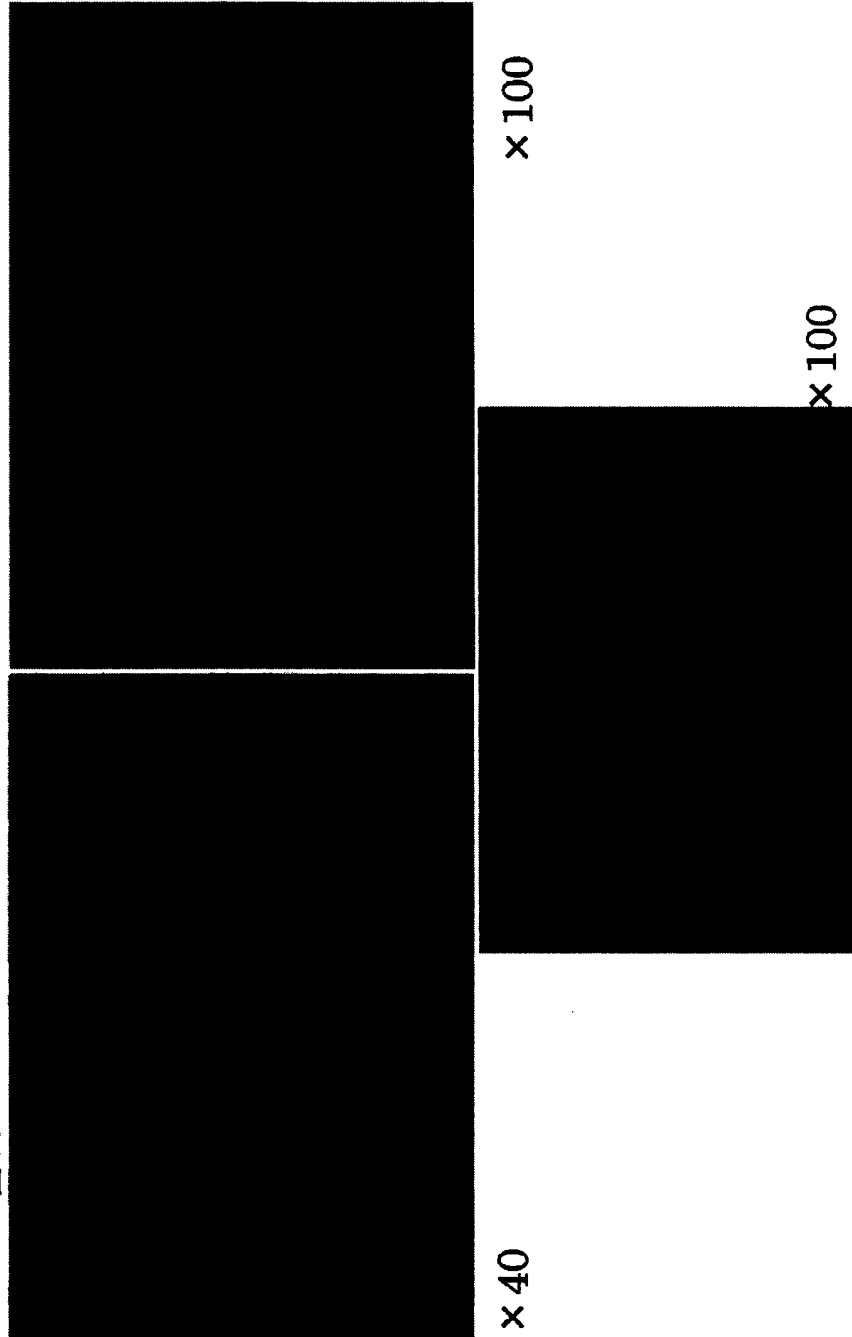


Fig. 39

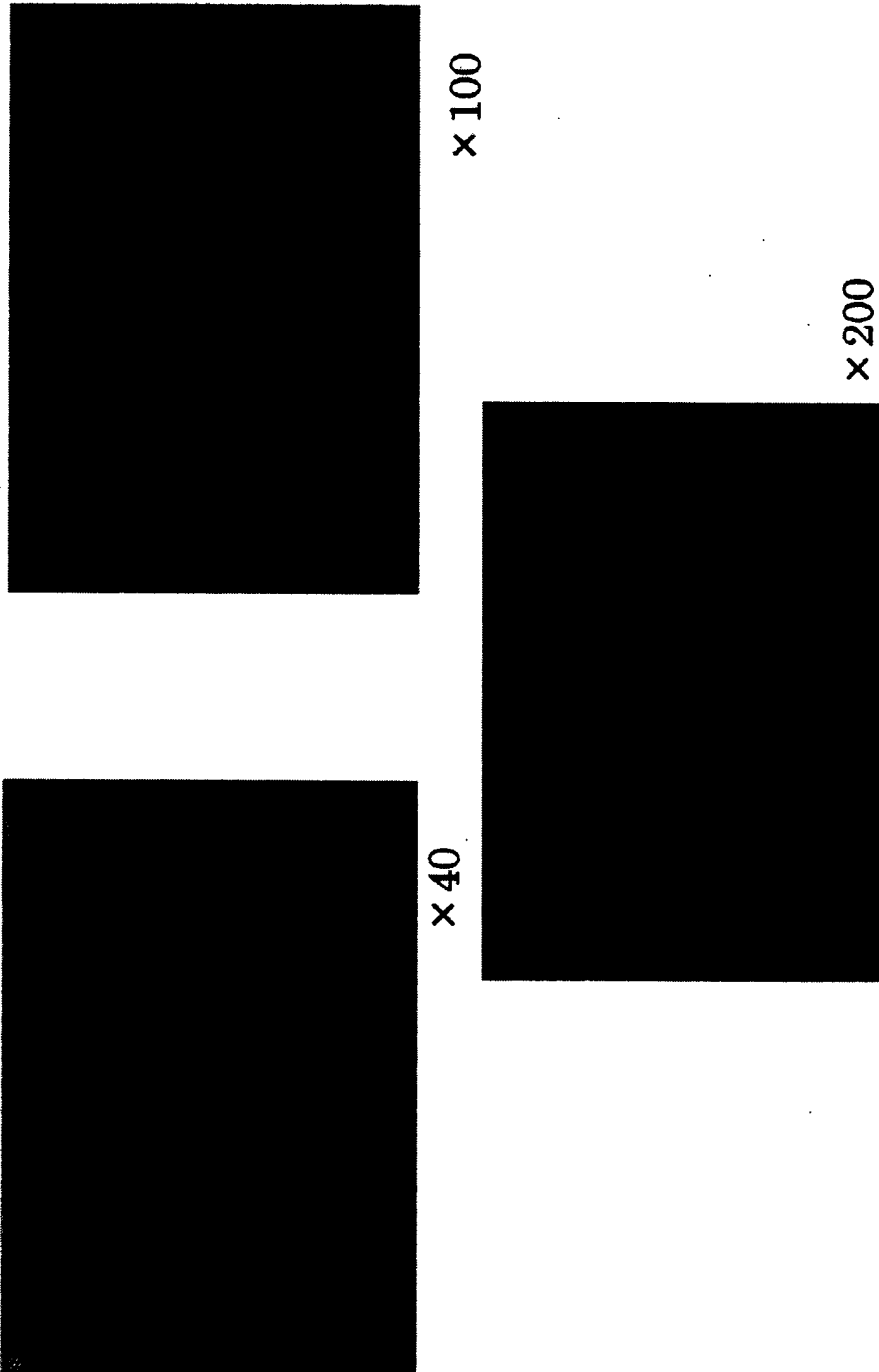
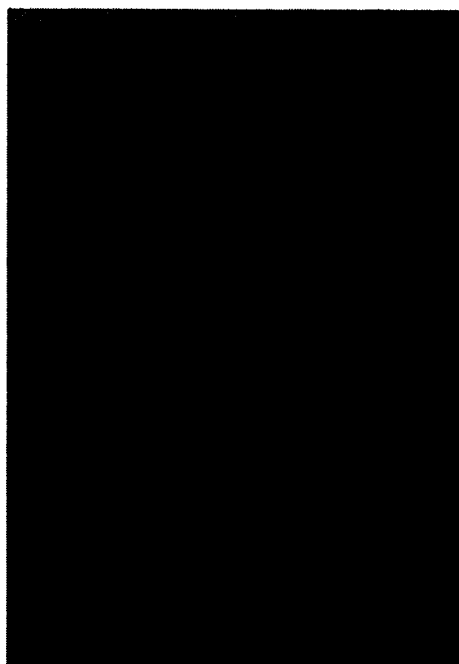


Fig. 40



× 100



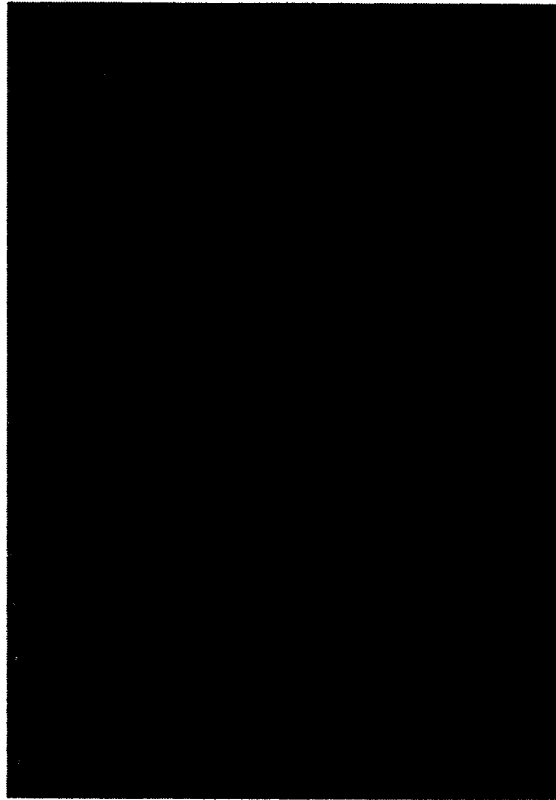
× 40

Fig. 41



x 100

Fig. 42



x 100



x 40

Fig. 43

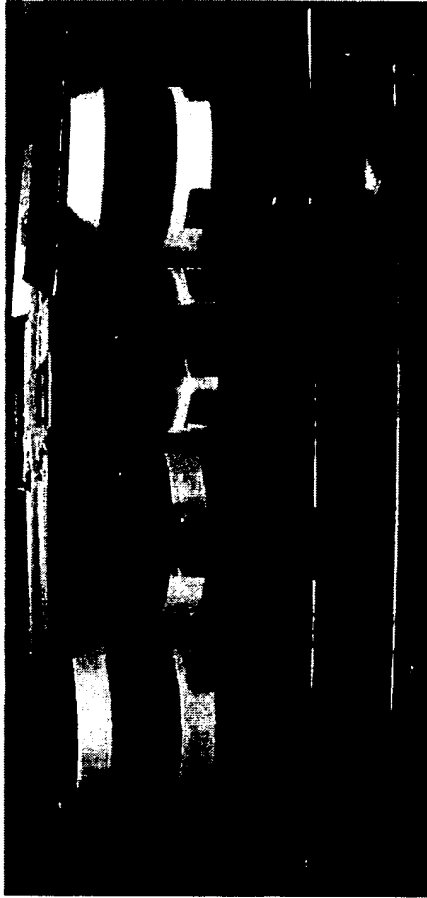


Fig. 44

*HE staining, X200, gamma-irradiation: 15kGy



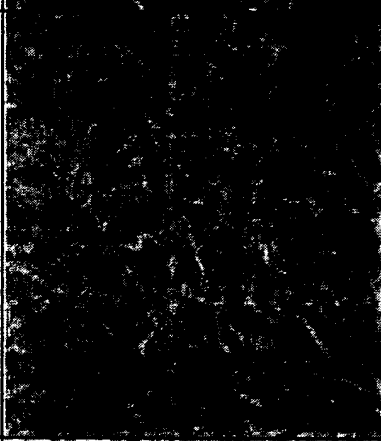

native					remaining cells observed	No remaining cells	No remaining cells	No remaining cells
--------	--	--	---	--	-----------------------------	-----------------------	-----------------------	-----------------------

Fig. 45A

*DNA assay/sample ($\mu\text{g}/\text{mg}$), gamma-irradiation: 15kGy

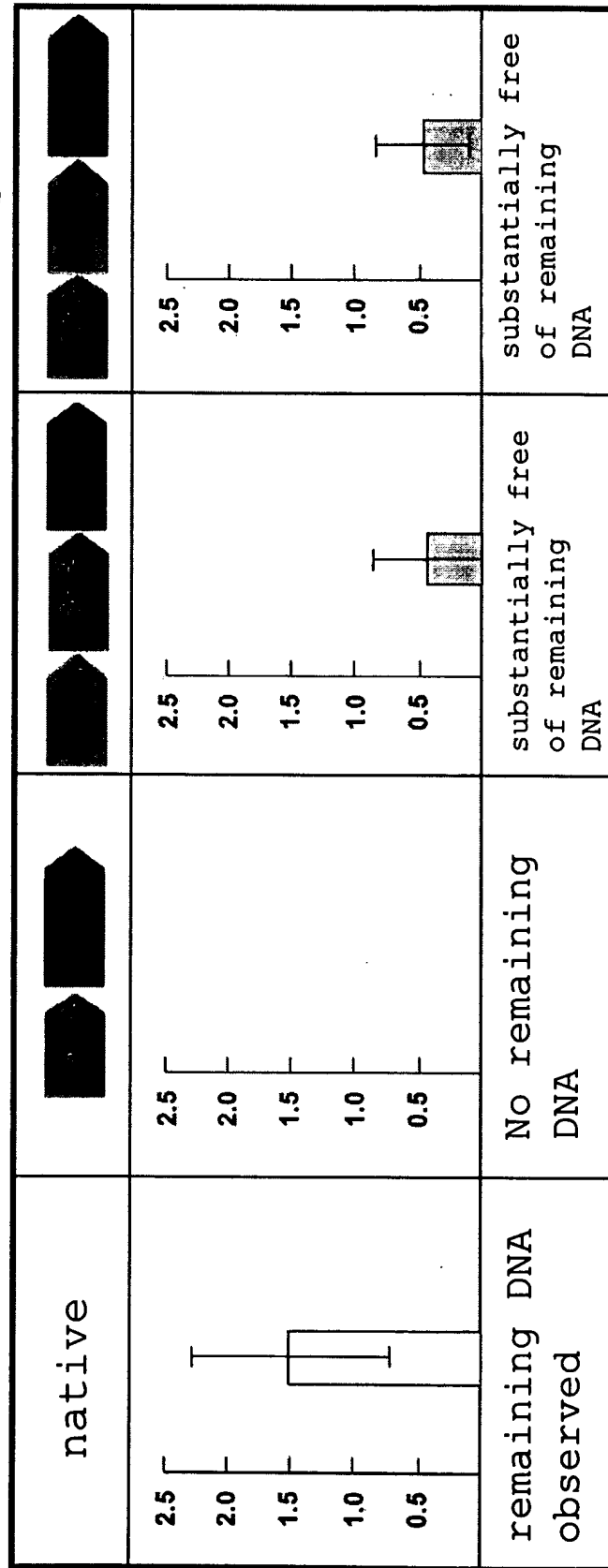


Fig. 45B

*DNA assay/sample ($\mu\text{g}/\text{mg}$), gamma-irradiation: 15kGy

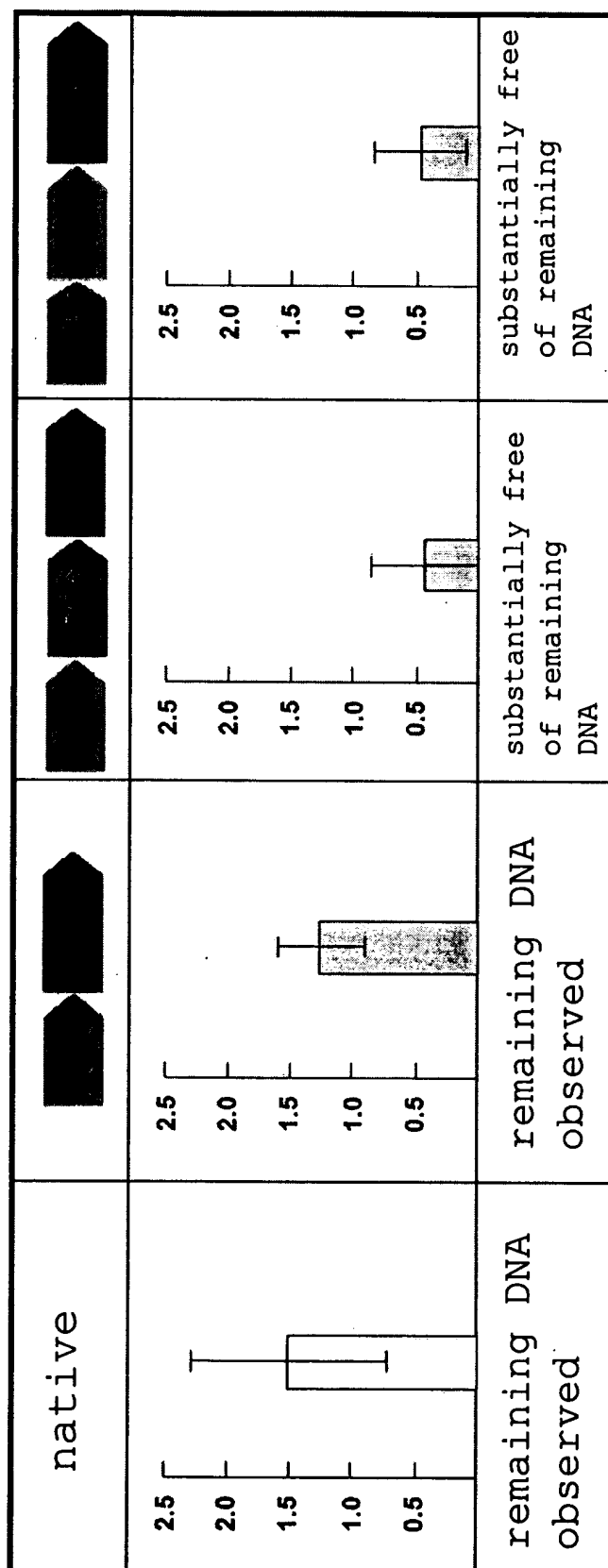


Fig. 46

*protein assay/sample (mg/mg), gamma-irradiation: 15kGy

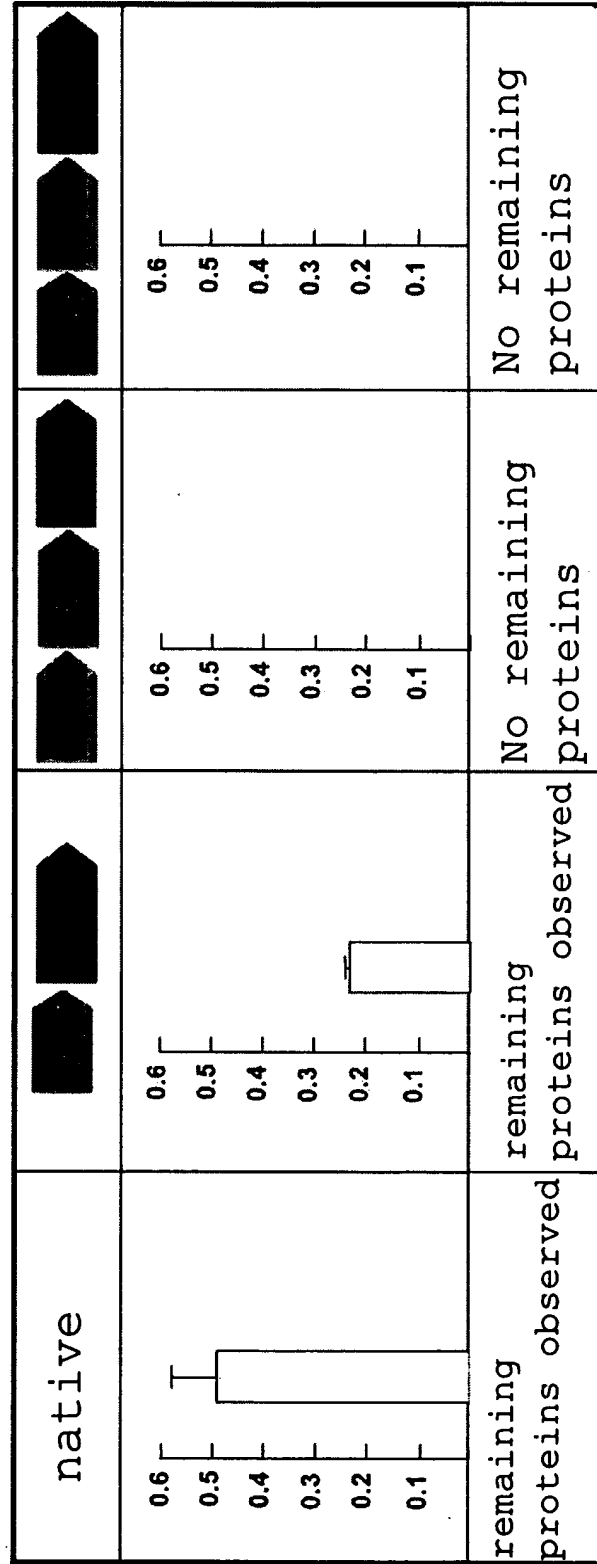


Fig. 47

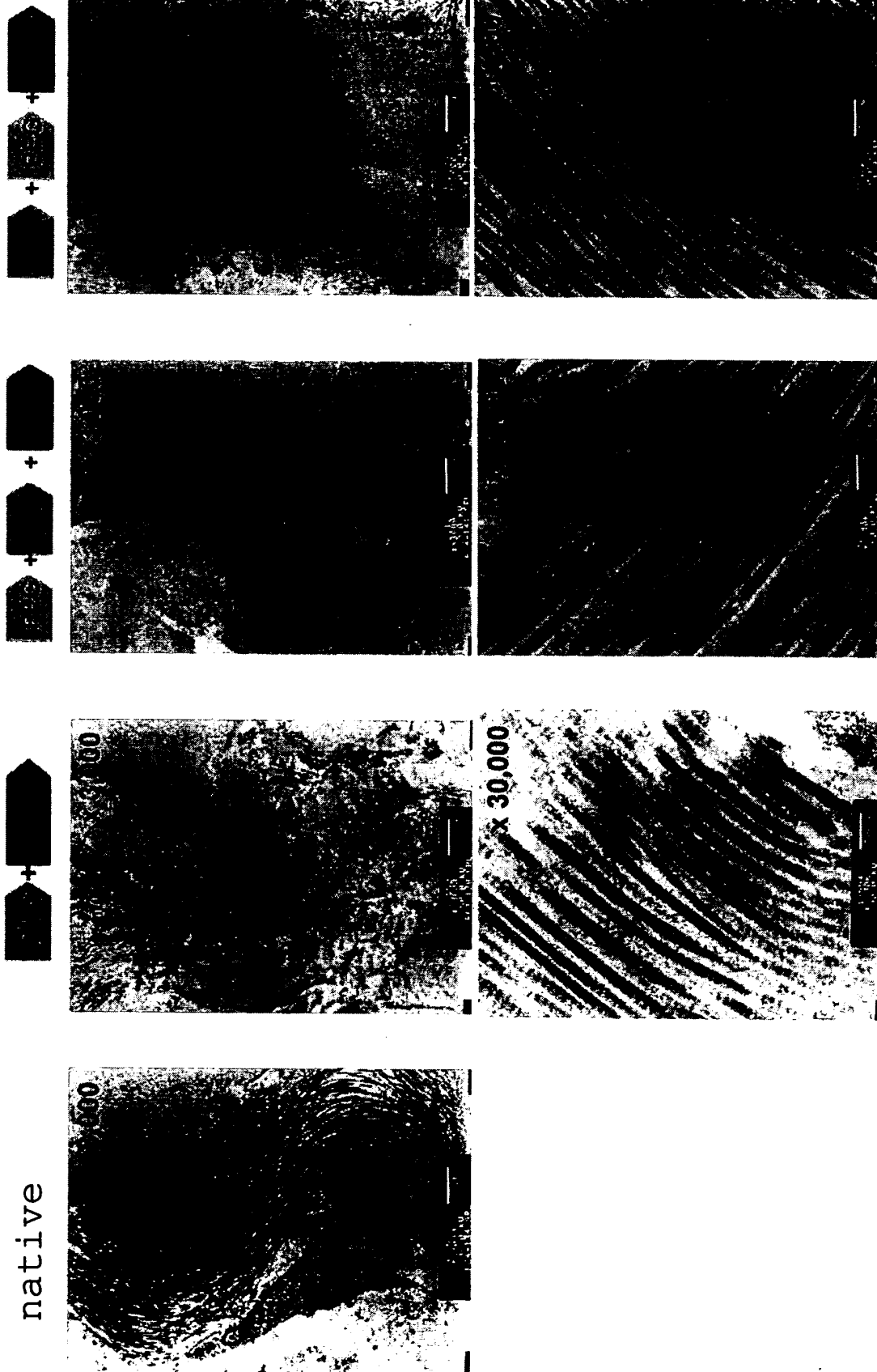


Fig. 48

*Tensile strength test/maximum load (N), gamma-irradiation: 151Gy

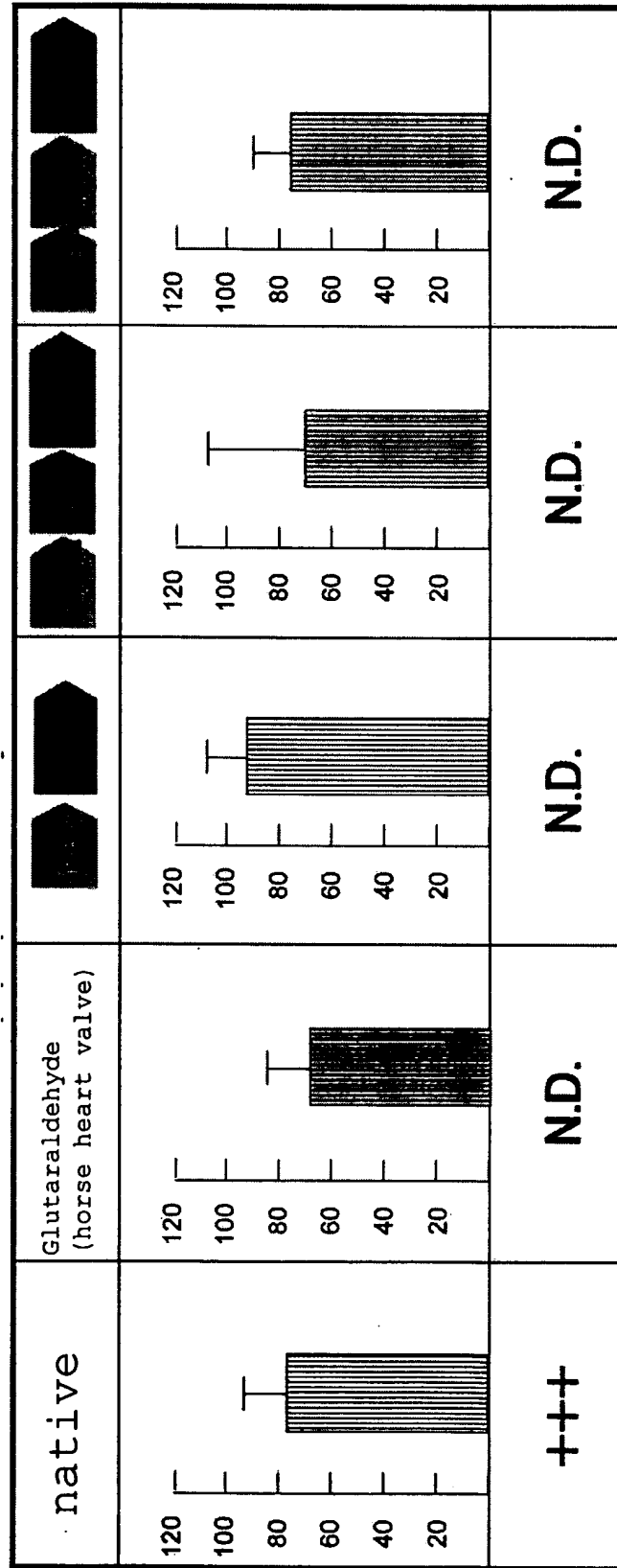


Fig. 49

*HE staining, one week after transplantation, gamma-irradiation:15kGy












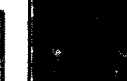


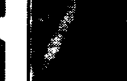



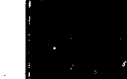
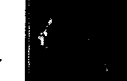







native	Glutaraldehyde (horse heart valve)						
Immunological rejection reaction observed	Immunological rejection reaction observed						
Immunological rejection reaction observed	Immunological rejection reaction observed						
Immunological rejection reaction observed	Immunological rejection reaction observed						
Immunological rejection reaction observed	Immunological rejection reaction observed						

Fig. 50

*HE staining, two months after transplantation, gamma-irradiation:15kGy





native	Glutaraldehyde (horse heart valve)				No immunological rejection reaction
					No immunological rejection reaction
Immunological rejection reaction observed	Immunological rejection reaction observed	No immunological rejection reaction	No immunological rejection reaction	No immunological rejection reaction	

Fig. 51

*von Kossa staining , two months after transplantation, gamma-irradiation:15kGy




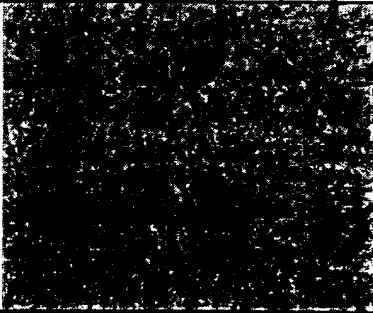
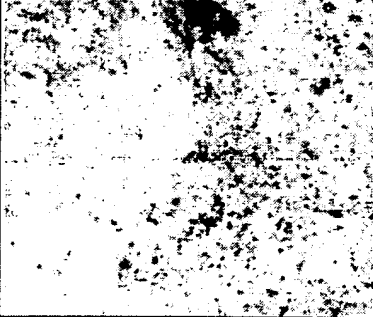
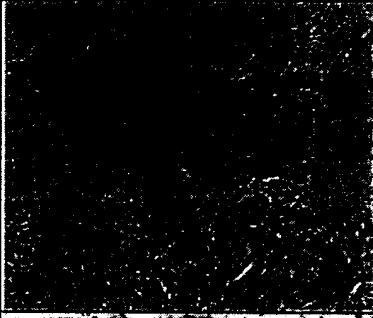
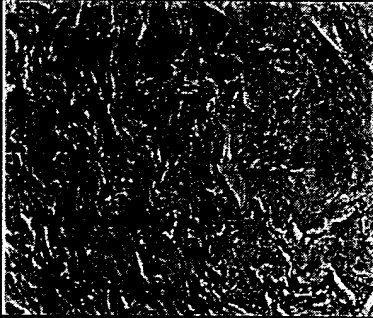
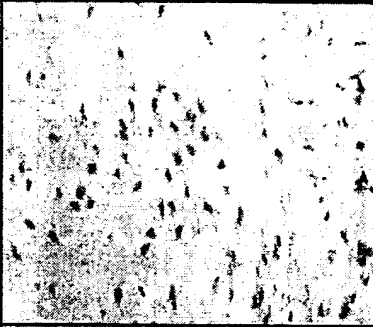
native	Glutaraldehyde (horse heart valve)			
				
No calcification reaction	Calcification reaction observed	No calcification reaction	No calcification reaction	No calcification reaction

Fig. 52

*Investigation of the calcification/sample (mg/mg), two months after transplantation, gamma-irradiation:15kGy

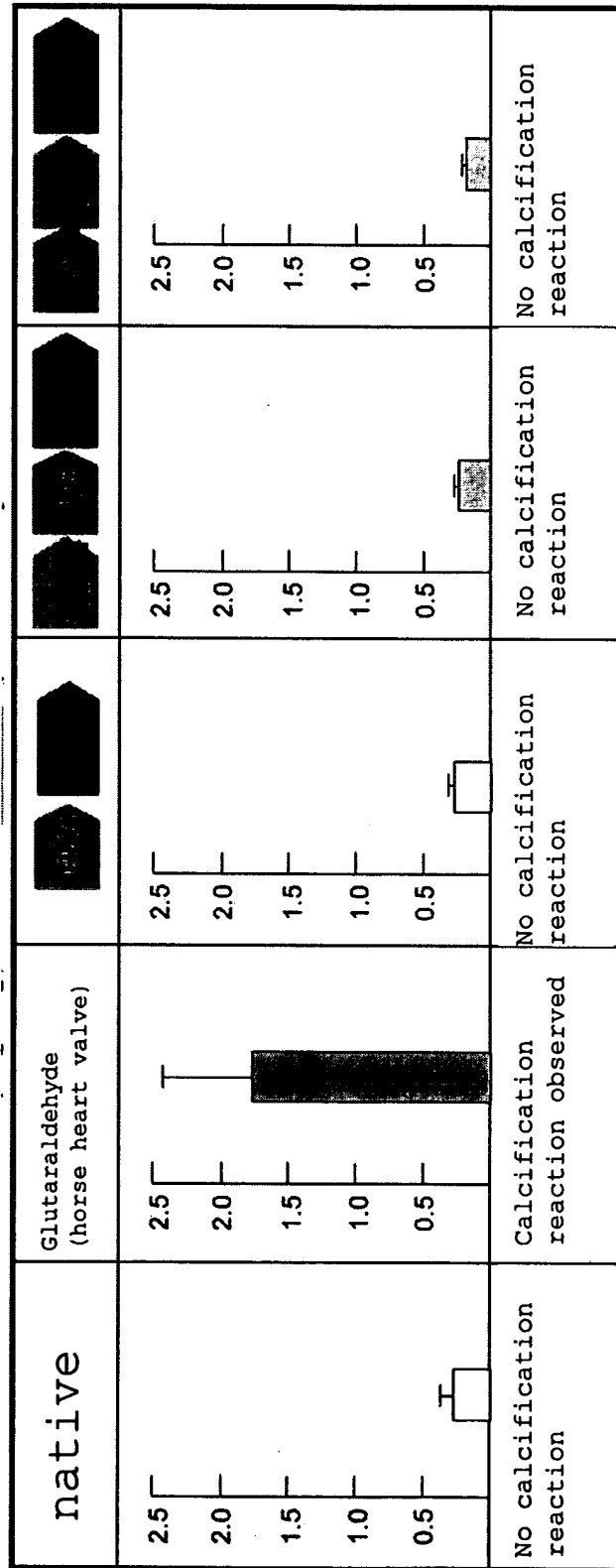


Fig. 53

	Native	PEG+DNase	x 100
No irradiation			N.C. rhesus monkey
Gamma-irradiation (100kGy)			

Fig. 54

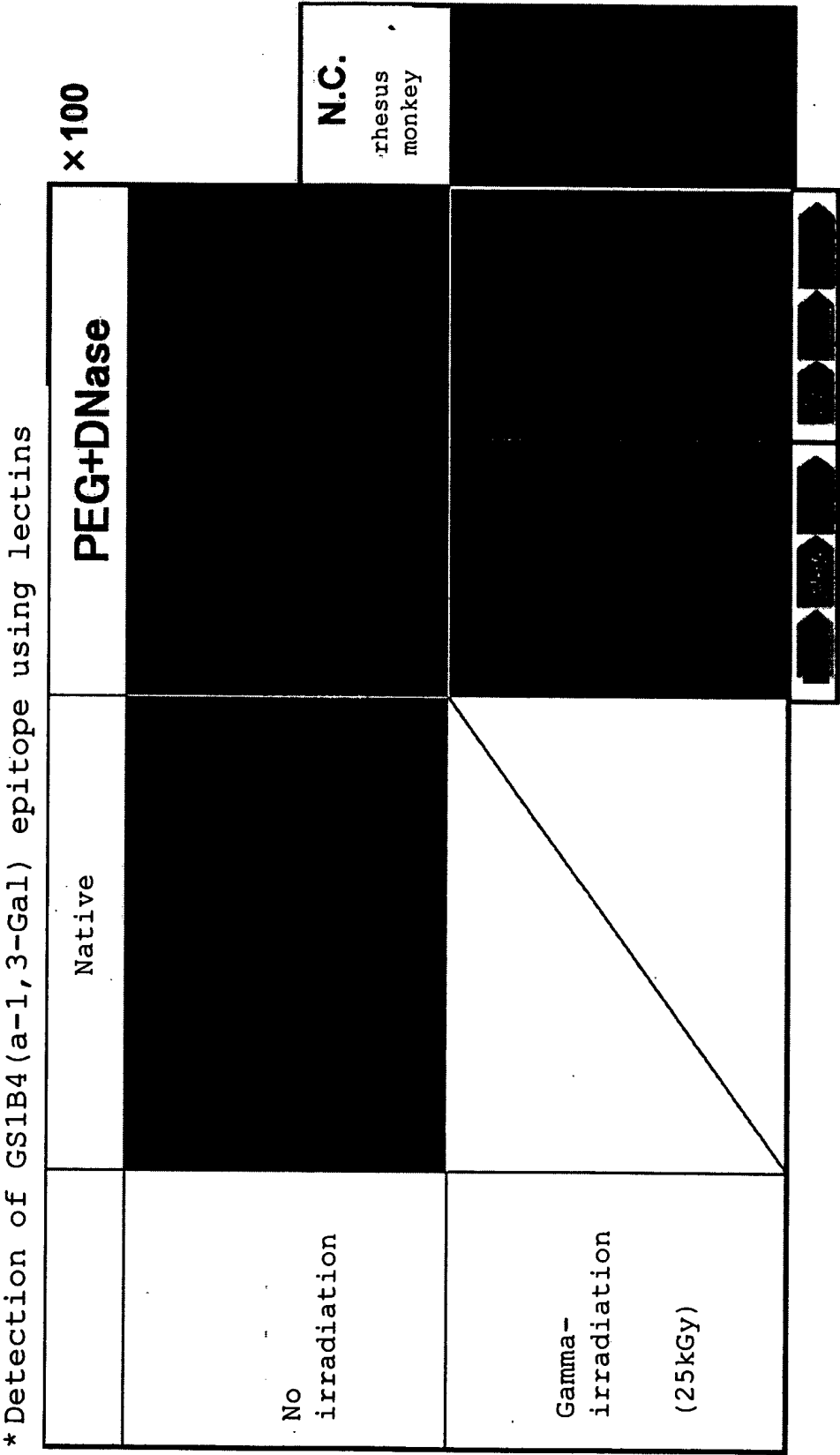


Fig. 55

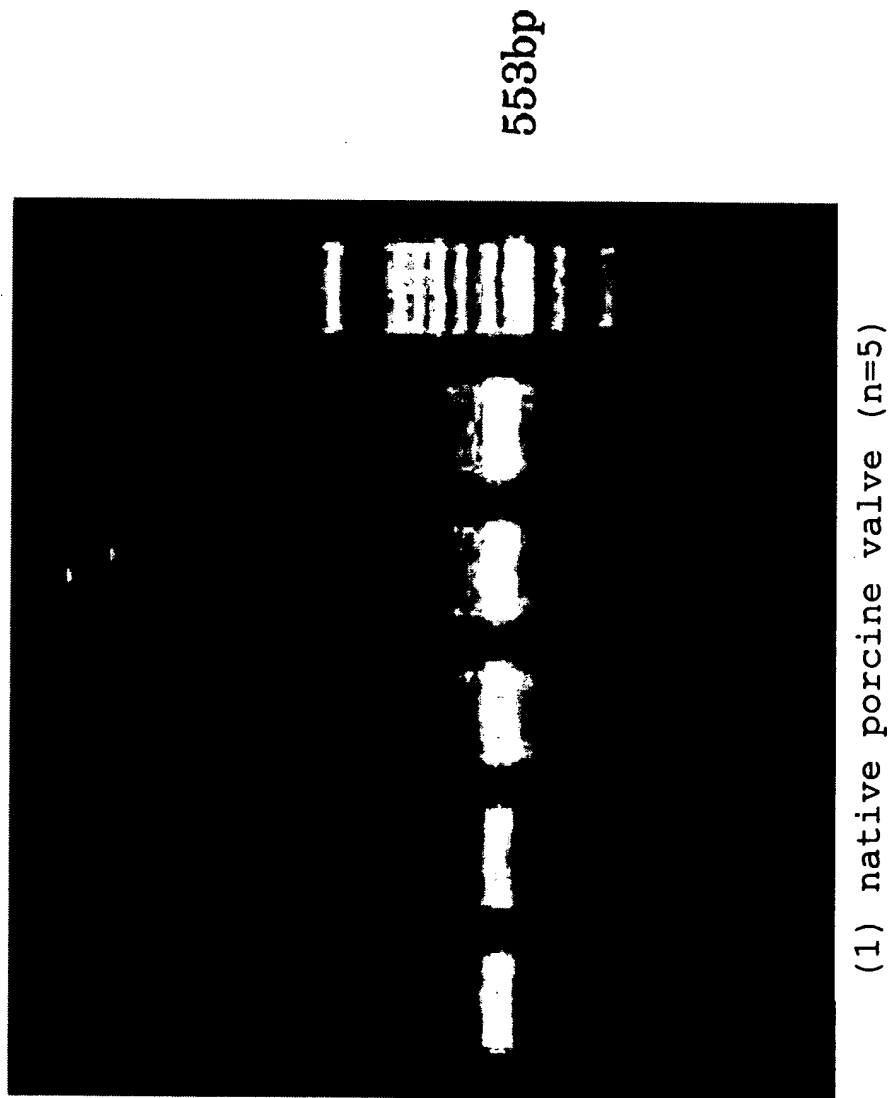


Fig. 56

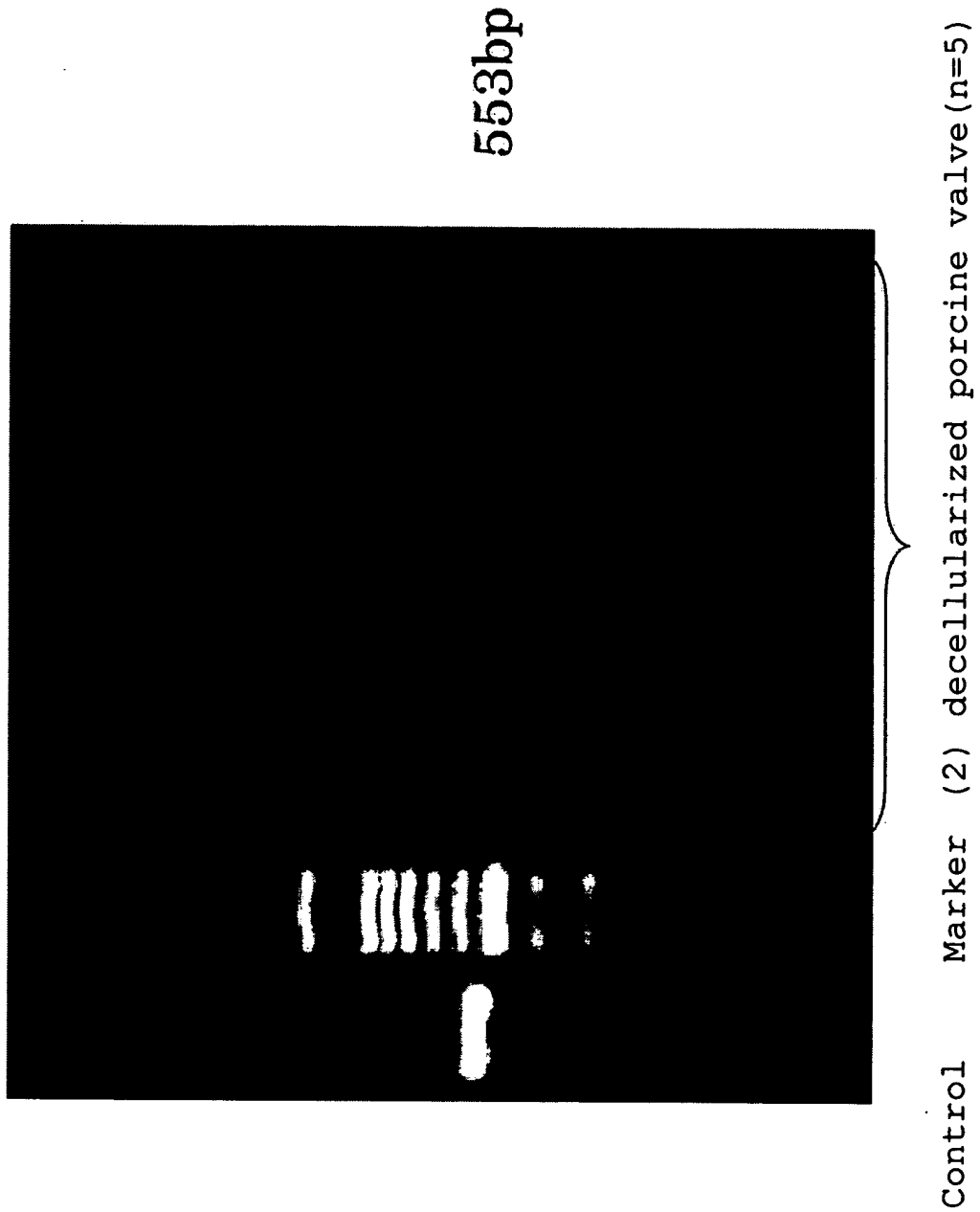
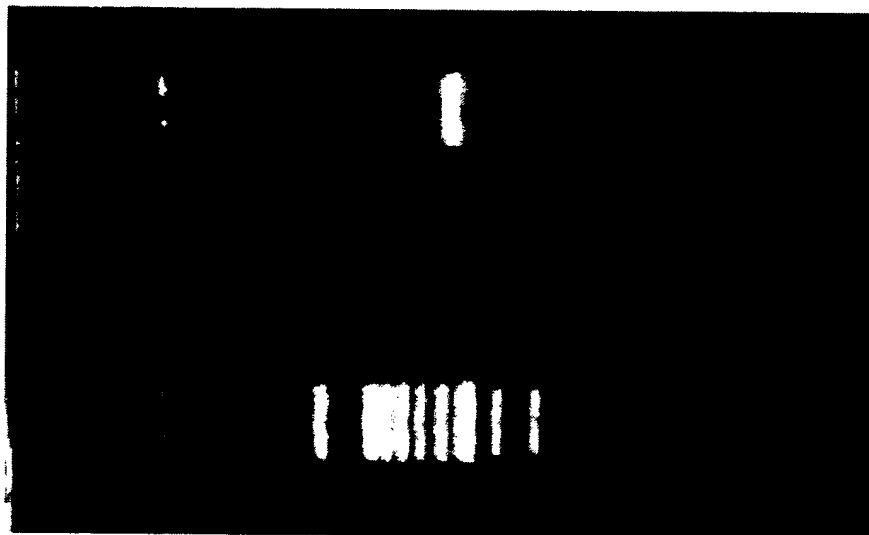


Fig. 57



553bp

- (1) native porcine valves
(2) the decellularized porcine valves removed from the host thirty days after transplantation
(3) the decellularized porcine valves removed from the fifty-six days after transplantation

Marker (3) (4) (1)

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